Medical Device Application

ARTG No : 97770

AIMD
Status: Approved

Application Change history

Selected for Compulsory Application Audit Level 2 (s.22 , 06/05/2003)
sub 2003/112 (, 18/08/2003)

Application Progress Date	
Date received:	22/04/2003
Review Information	
Review flag:	Class or Type requires review
Auto review required:	No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes
Is the device intended to be invasive: Yes
Is the device, or any form of the device, intended for single use: Yes
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device contain Human Blood or its components: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Is the device formulated: No
Does the product contain a medicine that is supplied separately in the Australian Market: No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No
Is the device software or does it incorporate software?

Application Summary	
Application ID:	030422-WEBE-5LU7L3
Sponsor's own reference:	8637 SynchroMed II Programmable Pumps
Application for:	
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	◯ Yes ◯ No

Will you be applying for listing of this product on the Prosthesis List?	◯ Yes ◯ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	◯ Yes ◯ No
Sponsor name:	Medtronic Australasia Pty Ltd
Sponsor ID:	837
Agent name:	
Contact details:	
Contact email:	

Manufacturer Information	
Manufacturer's evidence:	030116-WEBE-5HU56J : Neurostimulators, Leads, Accessories, Pumps, Catheters, Programmers, Software, Transmitter Goto
Manufacturer name:	Medtronic Inc (United States Of America)[9913]
Certificate issued under:	Council Directive 90/385/EEC (AIMD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Assessment body:	TUV SUD Product Service GmbH Zertifizierstellen [0123]
GMDN code:	Infusion pump, implantable, programmable[35687]
GMDN description:	A device that is implanted for delivering narcotics, short-acting anaesthetic agents, insulin, antineoplastic drugs or other agents. Dosage is controlled by drug concentration and/or by radio frequency (RF) signals from an external programming device. The catheter from the pump is tied into the epidural or the intrathecal space of the spinal canal or into a blood vessel.
Intended purpose:	Indicated when patient therapy requires the chronic infusion of drugs or fluids

Device Category Terms	
Device category 1:	Active implantable devices
Device category 2:	Anaesthetic and respiratory devices
Device category 3:	Electro mechanical medical devices

Product Details	
Unique Product Identifier:	Implantable Infusion Pumps

Attached Documentation

History

24/10/2003 4:03:43 PM [redacted] Approved.
10/09/2003 13:14:46 - ([redacted]) Supporting Documents Received.
06/05/2003 15:48:21 - ([redacted]) Supporting Documents Requested.
06/05/2003 15:48:10 - ([redacted]) Selected for Review.
02/05/2003 - ([redacted]) Full Payment Received.

Record	Date	
Fee:	Date Paid:	02/05/2003
	Date Decision:	24/10/2003

Start Dates		Finish Dates		Working Days
Application Received	22/04/2003	Payment Received	02/05/2003	8
Payment Received	02/05/2003	Selected for Review	06/05/2003	2
			Total Working Days	133

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DAS FORM 4.a	Medical Device Application Without an Audit Assessment Checklist		
Comes under	DAS SOP 4 Assessing an application without an audit		
Applicable to	Devices Applications Section	Authorised by	[redacted] Director, DAS
Date issued	21 Jul 2021	Version #	1.0

Application Details

Submission ID	DA-2022-04963-1
Application ID	DV-2022-DA-12694-1
TRIM Reference	E22-576145
Sponsor Name	Medtronic Australasia Pty Ltd
Manufacturer Name:	MEDTRONIC INC (United States Of America)[9913]
UPI/Sponsor's reference	SynchroMed II Programmable Pump
Classification	III (refer to comments below)
GMDN Term & Code	Infusion pump, implantable, programmable [35687]

Outcome of the assessment/recommendation:

☐ Seek advice from the delegate

☐ Application has failed preliminary assessment

☐ Sponsor requested to withdraw application

☐ Decision to include kind of device in ARTG according to S41FF

☐ Impose conditions under S41FO

☐ Select application for audit under S41FH

☒ I confirm that I have the appropriate delegation under the *Therapeutic Goods Act 1989*

Name	s.22		
Signature	Signed electronically	Date	10/06/2022

Name			
Signature	Signed electronically	Date	15/06/2022

Description of the device

Please include images and references to the relevant documents if required

The device is for an AIMD to Class III reclassification. As per the details provided in the application form, the application is intended to re-classify the ARTG entry 97770 to Class III in accordance with the updated classification rule.

The device is Sterile, single use, invasive NMD - Synchromed II IInfusion Pump Indicated when patient therapy requires the chronic infusion of drugs or fluids. It is single pack active device with a software that stores and dispenses drugs according to instructions programmed by the clinician.

Part 1 – Application

Information provided in the application – Manufacturer's Evidence	
Manufacturer's Evidence ID	DV-20060320-MC-016783-11
Conformity assessment document issued by (TGA Conformity Assessment Certificate/Notified body/MDSAP/US FDA/Health Canada/Japan)	Notified body
Regulator/Certification Body name and ID	TUV SUD Product Service GmbH Zertifizierstellen [0123]
Any relevant information (e.g. is certificate current and if it expired, has it been replaced and when; does the scope of the certificate cover the kind of device/was ME stated correctly, and if it was not, has this information been corrected and when; etc.):	The certificate is current and expiring on 26/05/2024
Does the Notified Body have accreditation to assess the kind of device (under Medical Devices Directive 93/42/EEC and/or Active implantable medical devices 90/385/EEC or MDR 2017/745?	☒ Yes ☐ No

Any other information if relevant:

TÜV SÜD ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICAT ◆ 認證證書

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-200.14.03

Product Service

EC Certificate

Full Quality Assurance System
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 039709 1246 Rev. 00

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product: **Implantable Infusion Pump Systems, Implantable Catheters**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report no.: 713158134

Valid from: 2019-10-04
Valid until: 2024-05-26

Date, 2019-10-04

s.22

Body :

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Country : Germany

Phone : +49 (89) 50084261
Fax : +49 (89) 50084230

Email : ps.zert@tuvsud.com
Website : http://tuvsud.com/ps

Notified Body number : 0123

Version(s): 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Last approval date : 13/01/2022

Legislations		
2014/53/EU Radio equipment	HTML	PDF
Regulation (EU) 2016/425 Personal protective equipment	HTML	PDF
Regulation (EU) 2016/426 Appliances burning gaseous fuels	HTML	PDF
2013/53/EU Recreational craft and personal watercraft	HTML	PDF
98/79/EC In vitro diagnostic medical devices	HTML	PDF
Regulation (EU) 2017/746 on in vitro diagnostic medical devices	HTML	PDF
2006/42/EC Machinery	HTML	PDF
93/42/EEC Medical devices	HTML	PDF
90/385/EEC Active implantable medical devices	HTML	PDF
2014/30/EU Electromagnetic compatibility	HTML	PDF
Regulation (EU) 2017/745 on medical devices	HTML	PDF

Information provided in the application – Manufacturer's Evidence	

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"
Paragraph 41FD(c) – Is the kind of device correctly classified according to the medical device classifications? (Medical devices are classified based on its intended purpose, refer Division 3.1 and Schedule 2 or Schedule 2A for IVD of MD Regulations) Provide relevant information, including Class of the device, classification rule(s) that apply and justification if required below:	☒ Yes ☐ No ☐ N/A

5.1 Medical devices incorporating a medicine

(1) This clause applies to a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

(a) if used separately, would be a medicine; and

(b) is liable to act on a patient's body with action ancillary to that of the device.

(2) The device is classified as Class III.

Is this medical device one of the kind specified under MD Regulation 4.1 made for the purposes of section 41EA that requires the manufacturer to have a TGA conformity assessment certificate before an application for inclusion of that device in ARTG can be made, and no such certificate is in force? If it is not, provide relevant information below:	☐ Yes ☐ No ☒ N/A
Is application accompanied by the kind of information and in a form determined for the classification of medical device? (Refer Table 2 of the guidance '*Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices*') If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Preliminary assessment

N/A means 'Not application and/or "not enough information to be assessed"

EU	Annex 2.3	Annex 2.4 - Design Examination
EU 90/385/EEC[6] (AIMDD) for AIMD	• Annex 4 (**for non-sterile devices** where specific batches are included on the certificate), or • Annex 5	Annex 3

Paragraph 41FD(f) – Have the appropriate conformity assessment procedure or requirements, comparable to the conformity assessment procedure been applied to the kind of device? If not, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Paragraph 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures/ comparable procedures, or have procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that information can be obtained from the manufacturer within the period specified in the regulations? If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Is the device in the application a medical device used for a special purpose (according to Regulation 3.10), e.g. procedure pack? If so, provide relevant information below:	☐ Yes ☒ No ☐ N/A

Part 2 – Application Assessment

Application assessment	N/A means 'Not application and/or "not enough information to be assessed"
Was the application made for a kind of device?	☒ Yes ☐ No ☐ N/A
Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)? Provide any relevant information below:	☒ Yes ☐ No ☐ N/A
For Class III and AIMD, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind? If the UPI does not appear to be correct, provide relevant information (including if it has been amended/corrected in the application, or if other application is required, etc.) below:	☒ Yes ☐ No ☐ N/A

Unique Product Identifier: SynchroMed II Programmable Pump

Current products

Id.	Product name
169031	SynchroMed II Programmable Pump - Infusion pump, implantable, programmable

For Class III and AIMD, are the variants stated in the application correct according to the information provided? If the variants do not appear to be correct, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Number of products: 2

Product details: Product variant info.

Code	Range	Description
36	20 to 40mL	Volume (mL)

Variant List

#	Variant type	Variant range
1.	Volume (mL)	20mL
2.	Volume (mL)	40mL

Application assessment	N/A means 'Not application and/or "not enough information to be assessed"
Does the intended purpose stated in the application appear to be correct? Does it indicate any concerns? Is it consistent with the GMDN code selected in the application? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A ☐ Yes ☒ No ☐ N/A ☒ Yes ☐ No ☐ N/A
Intended purpose: Indicated when patient therapy requires the chronic infusion of drugs or fluids -Application **Intended purpose:** Indicated when patient therapy requires the chronic infusion of drugs or fluids -ARTG entry	
Are there any other information/device product characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc.)? Are the device characteristics consistent with the intended purpose of the kind of device, GMDN code selected in then application, etc.? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A ☒ Yes ☐ No ☐ N/A
Are there any known concerns about the device (specifically or in general) such as the device is a vaginal mesh or EC Certificate was issued by a notified body of concern, e.g. withdrawal from the MDD accreditation). Refer "Hot Topics" R16/869138 Provide relevant information below:	☐ Yes ☒ No ☐ N/A

Information attached with the application	N/A means 'Not application and/or "not enough information to be assessed"
Was any other information provided with the application? If yes, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A
Design Examination Certificate - DE I7 18 02 39709 01163.pdf	

Information attached with the application	N/A means 'Not application and/or "not enough information to be assessed"
Declaration of Conformity [Provide the TRIM link] Is the Declaration of Conformity made in accordance to the appropriate Part of Schedule 3 of the MD Regulations and the scope covers the Device? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Labelling for the medical device [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Instructions for use (IFU) [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Any other information (e.g. data from the National Joint Replacement Registry). Provide relevant information below:	☐ Yes ☐ No ☐ N/A
Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?	☒ Yes ☐ No ☐ N/A

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

The application was made to re-classify the existing AIMD entry to Class III as part of the re-classification. Application was made during the first year of the transition period (before 24 No 2022) and therefore the application fee was waived.

Assessor's Name	[redacted]	Position Level	APS6
Signature	Signed electronically	Date	10/06/2022

Delegate's Checklist and Decision

Delegate's Checklist	
Do you have delegation for the purposes of section 41FDB of the Act (*Preliminary assessment* of applications)?	☒ Yes ☐ No
Do you have delegation for the purposes of section 41FF if application is finalised without the audit?	☒ Yes ☐ No
Have you checked that all requirements set out under section 41FF have been considered and met in making this decision?	☒ Yes ☐ No
Specify other if required: section 41FO	☐ Yes ☒ No
Other: section 41FL	☐ Yes ☒ No

Delegate's Decision	
Pass Preliminary Assessment **Note:** If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☒ Yes ☐ No
Include Kind of Device in ARTG	☒ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☒ No
Other: section 41FL	☐ Yes ☒ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

Delegate's Name	[redacted]	Position Level	APS6

Signature	Signed electronically	Date	15/06/2022

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D19-5922185	New document. Supersedes R16/879015 Updated to new template: MDB TEMP 2.1.c- Template for a FORM - Version 3.3 Reviewed/updated content to reflect current processes.	s.22	22 Jul 2021

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Preliminary review request and report - Clinical (DCS)

Application details

This section completed by DAS Assessor

Date of request	13/11/2023	
Submission ID	DA-2023-08940-1	
Application ID	DV-2023-DA-32797-1	
Sponsor name	Medtronic Australasia Pty Ltd	
Manufacturer name	Medtronic Inc 710 Medtronic Parkway Minneapolis MN 55432 United States Of America	
Reason for clinical review	Application supported by EU MDR certification	
Documents provided	☒ IFU and labels	Label: D23-4078334 Manual for pump: D23-4078329 Prescriber's manual: D23-4078323 Reference manual (indications, drug stability and emergency procedures): D23-4078313
	☐ For implantable devices (unless excluded*), PIL	D23-4078213
	☐ For implantable devices (unless excluded*), PIC	D23-4078199
	☐ Advertising material	
	☒ Clinical evaluation report (CER), signed and dated ≤ 2 years	D23-4078186

	☐ CV of clinical expert ☐ Risk management report, including FMEA ☐ For implantable devices, MRI safety evidence
Request comments	The sponsor also provided: • Cover letter D23-4078354 • TDAR D23-4078341 • CEAR D23-4078338
Submission TRIM reference	E23-355088

* Excluded devices are sutures, staples, dental filings, dental braces, tooth crowns, general (endosseous) dental implants, screws, wedges, plates, wires, pins, clips, connectors

Device description

Information from eBS device application form

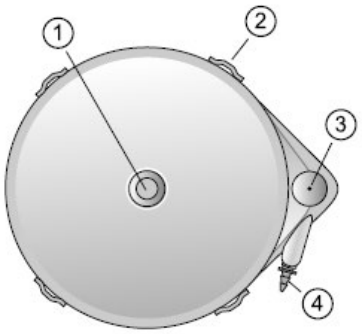
DAS to complete for Class III/AIMD, delete if not applicable. If there are multiple applications in the submission, add and complete a table for each application.

UPI	Synchromed lll 8667
Variant information	Total number of devices covered: 2 Variant type: Model number (see guidance docs); Model number (see guidance docs); Gauge (mm); Gauge (mm) Variant range: 8667-20; 8667-40; 24 (0.55); 22 (0.7)
Intended purpose	The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site
Functional description	The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a pump and a catheter. The catheter connects to the pump catheter port. The kit contains a drug infusion pump and two needles
Device classification	Class III
GMDN code and term	Intrathecal implantable infusion pump, programmable[46024]

Comments	

Information provided for the application – labels, IFU, advertising, CER etc.

Clinical Reviewer to complete. If there are multiple applications or devices in the submission, add and complete a table for each application or device.

UPI	Synchromed lll 8667
Device description	From Pump manual: **Intended purpose** The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. … **Description** The implantable Medtronic Model 8667 SynchroMed™ III programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8667 SynchroMed III programmable pump and a catheter. The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).  ***Figure 1.*** *Pump exterior view.* ① Reservoir fill port ② Suture loop ③ Catheter access port ④ Catheter port The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the internal pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of prescribed fluid directly into the implanted catheter for drug administration and diagnostic purposes. The prescribed fluid injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit). The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

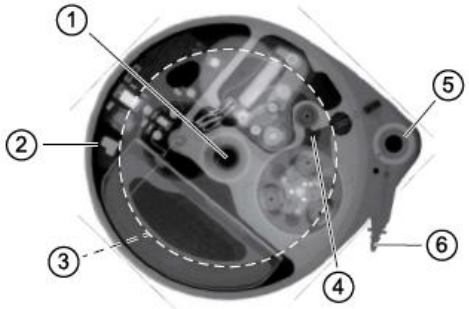


Figure 2. *Pump interior view.*

① Reservoir fill port
② Radiopaque identifier
③ Pump reservoir
④ Internal pump tubing
⑤ Catheter access port
⑥ Catheter port

...

Device specifications

Table 1. Shipping and operating values for the Model 8667 SynchroMed III pump

	Shipping	Operating
Fluid in reservoir	Sterile water	—
Shipping flow rate	0.006 mL/day	—
Infusion modes	Minimum rate	Single bolus Priming bolus Bridge bolus Simple continuous Flex Minimum rate Stopped pump
Alarms		
Critical alarm	Disabled	Enabled with an interval programmed
Non-critical alarm	Disabled	Enabled with an interval programmed

Table 2. Device specifications for the Model 8667 SynchroMed III pump[a]

	8667-20	8667-40
Pump		
Thickness (including septum)	19.6 mm	26.1 mm
Weight (empty/full)	146/166 g	152/192 g
Displacement volume	88 mL	118 mL
Diameter (including CAP)	87.5 mm	87.5 mm
Pump reservoir		
Volume	20.0 mL	40.0 mL
Residual volume	1.4 mL	1.4 mL
Fill volume at shipping from manufacturing	17.5 mL	37.5 mL
Reservoir fill port		
Septum puncture life	500 punctures	500 punctures
Catheter access port		
Septum puncture life	100 punctures	100 punctures
Flow rate		
Maximum programmable[b]	24 mL/day	24 mL/day
Minimum programmable[b]	0.048 mL/day	0.048 mL/day
Stopped pump maximum leakage	0.030 mL/day	0.030 mL/day
Bacterial retentive filter		
Pore size	0.22 µm (micron)	0.22 µm (micron)
Power source		
Battery	Lithium / carbon monofluoride - silver vanadium oxide	Lithium / carbon monofluoride - silver vanadium oxide
Longevity	Rate dependent (Figure 3)	Rate dependent (Figure 3)
Radiopaque identifier	NFY	NFY

Table 2. Device specifications for the Model 8667 SynchroMed III pump[a] (continued)

	8667-20	8667-40
Reservoir pressure	20.68 kPa to 34.75 kPa	20.68 kPa to 34.75 kPa
Expected lifetime	The pump has a service life of at least five (5) years operation up to a 0.910 mL/day flow rate from the day of implant until it reaches end of service.	The pump has a service life of at least five (5) years operation up to a 0.910 mL/day flow rate from the day of implant until it reaches end of service.

[a] All measurements are approximate.

[b] Actual limits depend on pump calibration constant and selected infusion mode.

The pump is implanted in a subcutaneous pocket in the lower abdomen.

For use in adult and pediatric patients, for >30 days.

From the Reference manual, the following drugs can be used with the pump:

	Table 1. Medtronic implantable infusion systems are approved for use with the following drugs

Infusion System is specifically approved for[a]	SynchroMed II	SynchroMed III	IsoMed
Preservative-free morphine sulfate sterile solution **The maximum approved concentration is 25 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate sterile solution.	X	X	X
Preservative-free morphine hydrochloride sterile solution **The maximum approved concentration is 25 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of preservative-free morphine hydrochloride sterile solution.	X	X	X
Preservative-free ziconotide solution for injection **The maximum approved concentration is 100 µg/mL.** A 0.9% solution of preservative-free sodium chloride injection can only be used with preservative-free ziconotide sterile solution after the initial fill of the pump with this drug.	X	X	—
Baclofen injection **The maximum approved concentration is 2 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of baclofen injection.	X	X	X

[a] Refer to the appropriate drug labeling for a complete list of indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.
X Specific pump is approved for use with drug.
— Specific pump is not approved for use with drug.

Device configurations & variants

Variants: 20mL and 40mL pump reservoir volumes

System or procedure pack

From IFU:

Package contents

- Pump
- Needle, 22-gauge (black sheath)
- Needle, 24-gauge (purple sheath)
- Product literature
- Registration form
- Patient identification card

SynchroMed III Programmable Infusion System consists of:

- SynchroMed III programmable pump
- intrathecal catheter
- refill kit – used to refill pump reservoir through refill septum
- catheter access port (CAP) kit
- wireless clinician programmer
- Personal Therapy Manager (which include communicators) – allows patient to activate delivery of physician programmed supplemental bolus doses of drug.

	• software Under this table is a diagram of the entire system.
Accessories or compatible devices	See above
Comments	

Note: ***Unique product identifier (UPI)*** is only relevant for Class III/AIMD devices as it forms part of the "kind of medical device" by which these devices are entered in the ARTG. The UPI is given to the device by its manufacturer to identify the device and any variants. **Device name** is relevant to devices other than Class III/AIMD. For non-Class III/AIMD devices, the name of the device does not form part of the "kind of medical device" and is not recorded in the ARTG entry.

From the notified body's CEAR:

1.1.8 Accessories and device combinations (MDR Annex II Sections 1.1(h), 1.1(i))

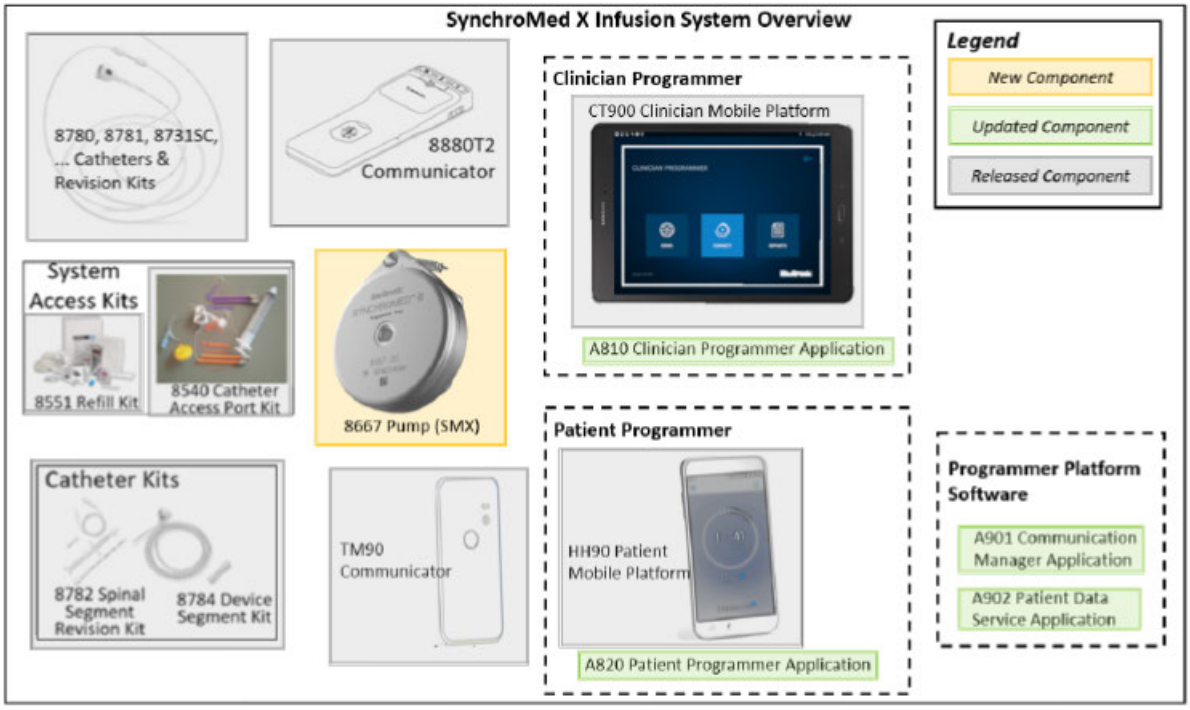


Figure 2 **SynchroMed III Infusion System, containing the Pump and devices necessary for fulfilment of its intended purpose.**

Application background

Conformity assessment documents accompanying application

These conformity assessment documents are linked to the application as Manufacturer Evidence or attached to the device application form. They were considered satisfactory in relation to the application passing preliminary assessment.

DAS to complete. If there are multiple QMS or product assessment documents, add and complete the relevant table for each document.

QMS

Regulatory authority	Notified body MDR
Type of document	MDR Annex IX, Chapter 1
Issuer	TUV SUD Product Service GmbH [0123]
Document identification	G12 039709 1291 Rev 06
Issue/decision date	6/04/2023
Expiry date	2/07/2025

Product assessment ☒ Yes ☐ No

Regulatory authority	Notified body MDR
Type of document	MDR Annex IX, Chapter 2
Issuer	TUV SUD Product Service GmbH [0123]
Document identification	G12 039709 1291 Rev 06
First issue/decision date*	27/10/2023 – subject device added
Latest issue/decision date^	27/10/2023
Expiry date	21/06/2027
Comments	TDAC: D23-4078345 Scope: **Classification:** Class III **Device Group:** J0401 - IMPLANTABLE PUMPS, ELECTRONIC **Basic UDI-DI:** 0763000B000197693 **Intended Purpose:** The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. **Device(s):** SynchroMed™ III Model No. 8667 Model Variant 8667-20 Model Variant 8667-40

* **First issue/decision date** is the date the document was first issued or a decision was made for the subject device.

^ **Latest issue date/decision date** and **Expiry date** may not be relevant or available, delete if appropriate.

Relevant TGA assessments and regulatory history

Information about whether the device has novel technological features or intended purpose, and whether the device, devices from the same family or related devices in a system/procedure pack (or accessories or compatible devices) have previously been reviewed by the TGA.

Reviewer to complete. For conformity assessments, review the root file for manufacturer and current and withdrawn rejected applications.

For ARTG inclusions, review current and cancelled ARTG entries (by GMDN, UPI), and current and withdrawn/rejected applications.

For post-market, review SARA database, Qlik IRIS Triage Dev app, and search for device name in TRIM.

If there are multiple certificates or ARTG entries, add and complete the relevant table for each certificate/document. Delete fields that are not relevant. Duplicate fields where necessary.

Novel technological features or intended purpose in Australia?	☐ Yes ☒ No

TGA conformity assessment certification ☐ **Yes** ☒ **No**

ARTG inclusion ☒ **Yes** ☐ **No**

Devices used with the SynchroMed II that are currently undergoing ARTG variation applications:

- SynchroMed II Clinician Programmer Application A810: ARTG 308884, start date 2018.
- A820 myPTM App: ARTG 358090, start date 2021.

These apps have been updated to allow use with the SynchroMed III, and to add a new workflow for Refill Only use cases, updated alerts, updated descriptions of myPTM app controls, and an updated name for the A810 to SynchroMed Clinician Programmer Application.

Post-market details ☒ **Yes** ☐ **No**

A search using TGA's Qlik app IRIS Triage Tool (v.07.02) revealed the following recall actions for the A810:

Recalls List

Recall Number	Date	Problem Desc	ARTG Num
RC-2020-RN-01348-1	2020-12-04	In the past two years, Medtronic has received eight reports where pump programming sessions were not fully completed and where the patient was released from the clinical setting with infusion therapy stopped. In these events, programmer warning screens notified clinicians of an incomplete programming session, however the programming sessions were not completed. In the reported events, the time to recognise the patient's pump was in stopped mode varied from 48 hours to 21 days. While the reported rate for this issue is very low (0.000517%), Medtronic is raising awareness of this situation to inform customers. Internal investigations have not identified any product defect or issue.	308884
RC-2020-RN-00619-1	2020-07-22	Since the introduction of the A810 SynchroMed II Software Application for use with the CT900 Clinician Programmer in June 2018, Medtronic has received three (3) reports of users observing an alert on the CT900 Clinician Programmer indicating that the pump programming update could not be completed. After investigation, it was determined that there was an error within a specific location of the pump memory and the A810 SynchroMed II Software application did not clear the error, resulting in an indication that the pump could not be updated. Memory errors are rare; some are resolved automatically by the pump, and others are resolved by manual configuration with the Clinician Programmer, allowing for continued programming activity and therapy delivery. With the assistance of Medtronic Technical Services, the three reported events were resolved with no patient harm.	308884

Other overseas regulator conformity assessment documents representing product assessment

These conformity assessment documents are additional to documents that accompanied the device application form.

Review:

- *Cover letter and information provided for the application, including CER.*
- *Relevant market authorisation databases for Health Canada and US FDA documents.*
- *Whether the UPI, variants and intended purpose are the same as the subject device.*

If multiple documents exist for a regulator or there are multiple devices, add and complete the relevant table each document/device. Delete fields that are not relevant.

EC Certification ☒ **Yes** ☐ **No** ☐ **Not known**

Certificate type	See above for documents accompanying application

Health Canada ☐ **Yes** ☒ **No**

US FDA ☒ **Yes** ☐ **No**

Approval by supplement:

Device	SynchroMed™ III Pump
Generic Name	Pump, infusion, implanted, programmable
Applicant	MEDTRONIC Inc. 7000 CENTRAL AVENUE NE MINNEAPOLIS, MN 55432-3576
PMA Number	P860004
Supplement Number	S404
Date Received	12/05/2022
Decision Date	10/06/2023
Product Code	LKK
Advisory Committee	General Hospital
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	Yes

Approval Order Statement
Approval of the SynchroMed III Pump, which includes updated firmware/software, manufacturing processes, labeling, and distribution temperature range.

Japan ☐ **Yes** ☐ **No** ☒ **Not known**

Singapore ☐ **Yes** ☒ **No**

Clinical review documentation

Clinical evidence report (CER)

Document identification & date	*Clinical Evaluation Report for SynchroMed III*, doc# NDHF1463-217401, version 3.0, dated 28/02/2023, 248 pages including appendices. CER covers the subject device and Model A810 programmer app and Model A820 myPTM app. Clinical evaluation strategy: • Design verification and validation testing, including on the SynchroMed III infusion system. • Claim of equivalence to SynchroMed II. • Clinical data from published literature, unpublished clinical studies, and PMS activities on the SynchroMed II infusion system, including PMCF data from Medtronic's Product Surveillance Registry (PSR).
Are the UPI/device name, any variants and intended purpose in the CER consistent with information provided with the device (IFU, labels etc)?	☒ Yes ☐ No Comments:
Does the CER include an evaluation of the clinical data?	☒ Yes ☐ No Comments:

Substantial equivalence claim ☒ Yes ☐ No

Comparator device:	SynchroMed II pump
Comparator type	☒ Predicate device ☐ Similar marketed device Comments:
Has evidence to demonstrate substantial equivalence of the comparator to the subject device been provided?	☒ Yes ☐ No Comments:

<u>Predicate's Australian regulatory history</u>

- ARTG 97770 for Class AIMD from 2003, then 389968 for Class III from 2022

1 . SynchroMed II Programmable Pump - Intrathecal implantabe infusion pump, programmable			
Product Type	Single Device Product	**Status**	Current
		Effective Date	10/06/2022
GMDN	46024 Intrathecal implantable infusion pump, programmable		
Functional Description	The SynchroMed II Programmable Pump is an implantable, battery-powered device that stores and dispenses drugs according to instructions programmed by the clinician. The pump has two reservoir sizes: Model 8637-20 has a 20ml reservoir volume, and the model 8637-40 has a 40ml reservoir volume.		
Intended Purpose	Indicated when patient therapy requires the chronic infusion of drugs or fluids		
Variant Information	Volume (mL)	40mL	
	Volume (mL)	20mL	

- A search using TGA's Qlik app IRIS Triage Tool (v.07.02) revealed:
  - 34 DIRs (27 incidents) of which three were investigated
  - A PMR related to the application then removal of a condition of inclusion resulting from an US FDA consent decree whereby corrections and enhancements were required for the pump and QMS: https://www.tga.gov.au/news/media-releases/medtronic-australasia-us-consent-decree-synchromed-drug-infusion-system#:~:text=Under%20a%20consent%20decree%20the,for%20continued%20supply%20of%20pumps.
  - The following recall actions and safety alerts, of which the latest action regarding MRI does not appear to have been agreed with the sponsor – see last recall in below list and E23-367872:

Recall Number	Date ↓	Problem Desc
RC-2019-RN-01577-1	2019-10-23	Medtronic advises that SynchroMed II Implantable Drug Infusion Pumps have a potential foreign particle inside the pump motor assembly which could interfere with motor gear rotation and lead to a permanent motor stall. A permanent pump motor stall will result in cessation of drug infusion therapy which may result in return of underlying symptoms and/or withdrawal symptoms. The source of the foreign particle has been identified and eliminated. As of 30-SEP-2019, Medtronic has confirmed five (5) reports of early permanent motor stall due to the presence of foreign particles from a manufacturing process.
RC-2017-RN-01495-1	2017-12-22	Medtronic is recalling the prior configuration of SynchroMed II implantable drug infusion pumps, as a new configuration is available with an enhanced motor design. This recall action only relates to unimplanted devices. Medtronic has received regulatory approval for a design change to the SynchroMed II implantable drug infusion pump. This design change of the motor decreases the potential for intermittent or permanent motor stall which can cause loss of therapy. All SynchroMed II pumps are now being manufactured and distributed with this change.
RC-2017-RN-00567-1	2017-05-08	Medtronic is updating information communicated in July 2011 (RC-2011-RN-00769-3) regarding the failure rate for reduced battery performance in Medtronic Model 8637 SynchroMed II pumps manufactured up to June 2011. Updated Failure Rate information due to this issue: - Pumps manufactured Mar 2005 through Dec 2010: 0.13% cumulative probability for pump failure at 72 months after implant. This rate remains within the failure rate upper bound of 0.2% reported in 2011. - Pumps manufactured from Jan 2011 through Jun 2011: 3.17% cumulative probability for pump failure at 72 months after implant. This failure rate exceeds the upper bound estimate of 0.2% reported in 2011. A patient with a pump exhibiting reduced battery performance may experience return of underlying symptoms and/or withdrawal symptoms. Patients receiving intrathecal baclofen therapy are at risk for baclofen withdrawal syndrome, which can lead to a life-threatening condition if not promptly and effectively treated.
RC-2017-RN-00065-1	2017-01-25	This action is a follow up to the July 2013 communication regarding the SynchroMed II priming bolus function and to inform that Medtronic is updating the Model 8870 software application card as well as the SynchroMed Infusion System labelling to address the issue. The software update will change the value displayed on the 8840 programmer for the SynchroMed II pump tubing volume from 0.199 mL to 0.140 mL. Over delivery of drug during priming bolus has the potential to lead to overdose symptoms in some patients. This software change mitigates the potential for unintended over-delivery of drug while still ensuring prompt therapy initiation. The SynchroMed II Infusion System Manuals were updated for the priming bolus function, and new guidelines for priming have been implemented.
RC-2016-RN-01458-1	2016-11-24	This communication is an update to Medtronic's March 2014 notification regarding the potential for SynchroMed II pump over-infusion. "Over-infusion" is defined as the delivery of more drug volume than the programmed rate, exceeding the pump's flow rate accuracy specification. Pump reservoir contents that are less than expected may indicate that the pump has over-infused. Over-infusion may or may not be associated with clinically relevant symptoms. When the pump delivers more drug volume than the programmed rate, patients may experience overdose symptoms. Patients may experience under-dose or withdrawal symptoms if the drug is depleted prior to the scheduled refill date from an over-infusing pump. The low reservoir alarm of an over-infusing pump will not sound if the pump reservoir is prematurely depleted. The low reservoir alarm is calculated from the pump's programmed delivery rate and is not a direct measurement of the actual drug volume remaining in the reservoir.
RC-2014-RN-00357-1	2016-11-07	Medtronic has detected an upward shift in reports of over-infusion, defined as an infusion rate exceeding the programmed rate by more than 14.5% as described in the labelling. When over-infusion occurs, it will result in a volume discrepancy at pump refill, where the volume withdrawn is less than the volume expected. The device does not measure actual reservoir volume and in the context of over-infusion the reservoir may empty entirely without activating an alarm. Over-infusion can result in a life-threatening overdose and/or drug withdrawal resulting from premature emptying of the pump. The onset of over-infusion has occurred as early as five months after implant and throughout the service life of the pump. Reports indicate that once a pump has started to over-infuse, infusion rates can continue to increase, in some cases abruptly. The device does not measure actual reservoir volume and in the context of over-infusion the reservoir may empty entirely without activating an alarm.
RC-2014-RN-00037-1	2014-01-23	The SynchroMed II pump software update will automatically correct the following two issues: 1) Erroneous Replace by Date: The updated software corrects the issue previously communicated in Medtronic's March 2012 (TGA Ref: RC-2012-RN-00260-3) i.e., In some circumstances after a pump's Elective Replacement Indicator (ERI) has occurred, the "Schedule to replace the pump by" date may be incorrectly displayed as a series of question marks (??/??/????), or as a date greater than 90 days from the ERI date, potentially leading to the pump reaching End of Service (EOS) prior to replacement. 2) Premature Reservoir Alarm: The updated software corrects the potential for premature low and empty reservoir alarms. These premature alarms are due to an incorrect calculation within the 8840 programmer software. The majority of these alarms occur within the clinic immediately following an interrogation.

RC-2013-RN-00636-1	2013-07-04	Within the SynchroMed pump, feedthroughs are components that provide an electrically insulated path for current to flow from the electronic circuitry to the motor. An electrical short can occur when ions from the drug solution and humidity permeate through the drug pathway tubing inside the pump and interact with the feedthrough over time. An electrical short circuit in a feedthrough may present as a motor stall or low battery reset/alarm and leads to a loss of or reduction in therapy which may result in the return of underlying symptoms and/or withdrawal symptoms.
RC-2013-RN-00677-1	2013-07-04	The SynchroMed priming bolus function is intended to quickly advance drug from the pump reservoir to the catheter tip to allow for therapy initiation while the patient remains under medical supervision. Although drug is not intended to be delivered to the cerebrospinal fluid (CSF) during the priming bolus, mixing of the drug and non-drug (sterile water/CSF) fluids occurs at the high infusion rates used during a priming bolus. Mixing results in the unintended delivery of drug prior to the end of the programmed bolus, as well as dilution of some of the drug remaining in the catheter at the end of the bolus. Patients will receive unintended drug at a high rate of infusion in the CSF during the priming bolus, and a period of reduced concentration of drug will occur following the priming bolus.
RC-2013-RN-00678-1	2013-07-04	The Clinician Refill Reference Card for SynchroMed Implantable Infusion Systems that was originally distributed with the January 2011 Safety Alert (TGA Ref.: RC-2010-RN-01266-3) related to pocket fills has been updated to align with new product labelling. The January 2011 Medical Device Correction letter provided important reminders concerning the potential for a pocket fill during a SynchroMed II or SynchroMed EL implantable drug pump refill procedure, and important patient management recommendations. A pocket fill is the inadvertent injection of all or some of the prescribed drug into the patient's subcutaneous tissue, which includes the pump pocket, instead of the pump which can lead to life-threatening symptoms, serious patient injury, or death due to overdose or underdose.

RC-2012-RN-01134-1	2012-11-08	Use of unapproved drugs with SynchroMed pumps can result in an increased risk of permanent motor stall and cessation of drug infusion. The use of unapproved drugs can lead to intermittent or permanent pump motor stalls which may be reported as a loss of or change in therapy. Therapy changes could potentially result in serious injury and/or death.
RC-2012-RN-00260-3	2012-03-09	In some circumstances after a pump's Elective Replacement Indicator (ERI) has occurred, the "Schedule to replace the pump by" date may be incorrectly displayed as a series of question marks (??/??/????), or as a date greater than 90 days from the ERI date, potentially leading to the pump reaching End of Service (EOS) prior to replacement.
RC-2011-RN-00769-3	2011-07-27	Medtronic has continued to analyse worldwide cases of reduced battery performance and is providing an update to the Hazard Alert issued in 2009. The recommemdations provided in 2009 in relation to patient management have not changed.
RC-2010-RN-01266-3	2010-12-23	Safety Alert information for the SynchroMed II and SynchroMed EL to remind Health Care Professionals of the correct technique to use, as per the IFU, when refilling these implanted infusion pumps to prevent pocket fills which is the inadvertent injection of all or some of the prescribed drug into the patients subcutaneous tissue to prevent the potential for drug overdose.

RC-2009-RN-00521-3	2009-07-07	Potential for reduced battery performance in a small percentage of Medtronic Model 8637 SynchroMed II pumps with batteries manufactured during two distinct time periods prior to April 2005.
RN-2008-0349	2008-05-14	A small number of Medtronic SynchroMed® II Implantable Infusion Pumps may have been manufactured without propellant. The missing propellant condition can cause drug dilution in the pump reservoir, leading to unknown drug concentration, and inconsistent or variable therapy results.
RN-2008-0056	2008-02-08	Formation of an inflammatory mass or granuloma which can sometimes occur at the tip of an intrathecal catheter used to deliver drugs via an implanted drugs infusion.
RC-2009-RN-00763-3	-	-

RC-2023-RN-01015-1	-	The MRI Guidelines Instructions for Use for Medtronic Model 8637 Implantable Infusion Systems (MRI Guidelines) indicate that during normal operations, the magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed II pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure. Medtronic recently identified that if the SynchroMed II pump switches into telemetry mode due to electromagnetic interference (EMI) from an MRI scan, while the pump is sounding an alarm, the pump will not resume drug delivery after leaving the MRI magnetic field, which is inconsistent with the current labelling. In this case, drug delivery will only resume after performing a post-MRI pump interrogation with the Clinician Programmer Personal Therapy Manager which will end telemetry mode.

Differences between the SynchroMed II and III

Overview of changes from the CER (p.8-9):

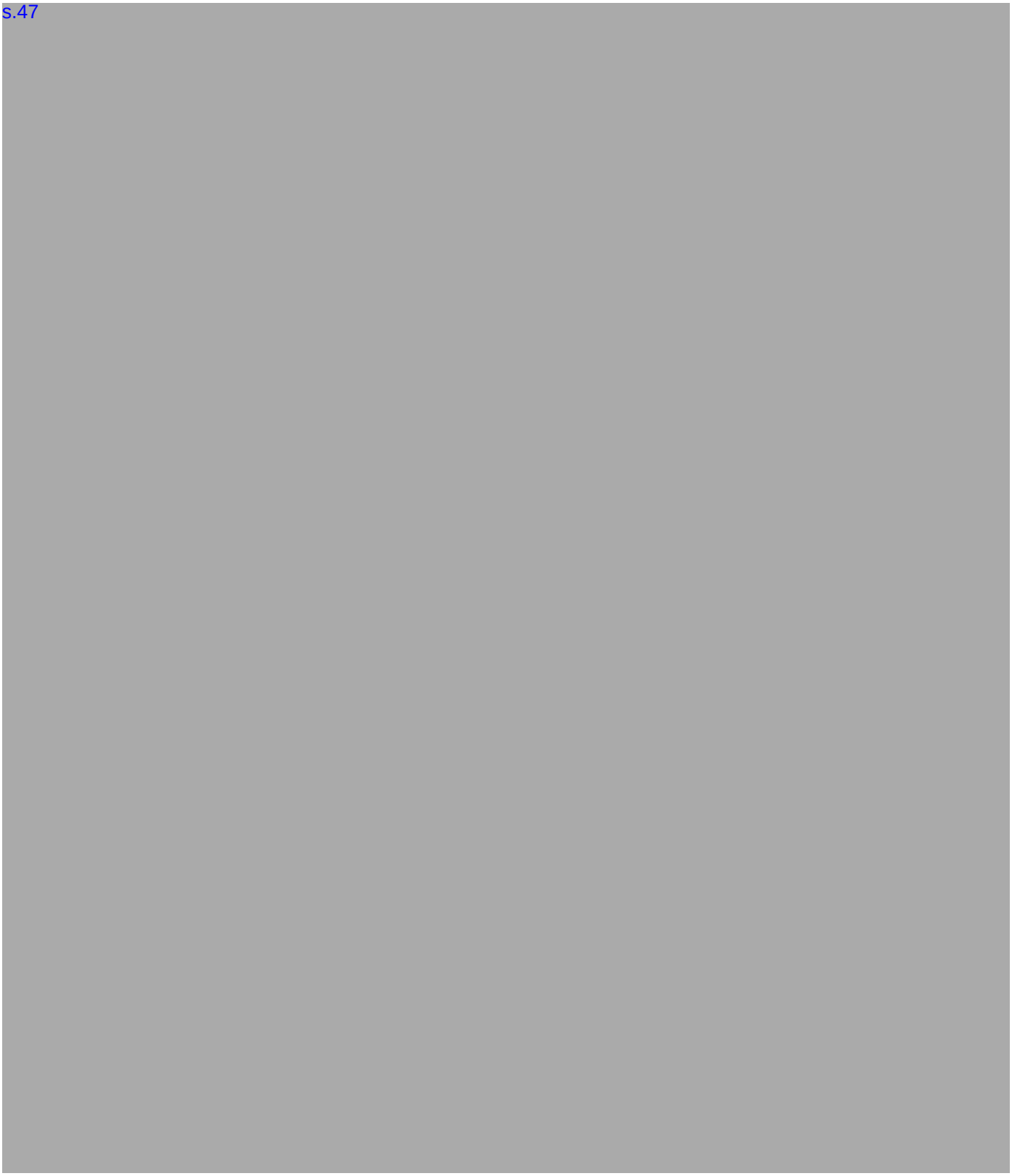
The SynchroMed III pump (Model 8667) replaces the SynchroMed II pump (Model 8637) with an updated hybrid circuit, including the IC's and firmware running on them. The SynchroMed III pump has the following changes:

- Pump model number (8667) and Brand Name (SynchroMed III)
- Face shield with new model number (8667)
- Electronics integrated circuit replacement
- Telemetry features for secure communication
- Firmware updates for compatibility with new Model A810 and Model A820 Applications
- Support for enhanced features, including updated alarms
- Increased telemetry/log sizes
- Support for boluses triggered by low reservoir conditions or events

- Over-Pressurization Mechanism (OPM) update for expanded distribution temperature range

Technical differences from CER (p.52-53):

s.47



The are apparently no biological or clinical differences between the devices.

In relation to clinical equivalency, following is stated (CER, p.55):

> The SynchroMed III system will be used for the same clinical conditions, same patient population, for the same kind of user. The SynchroMed III system will be used with the same drugs as the SynchroMed II system. The SynchroMed III pump will be implanted in the same site in the body using the same techniques as SynchroMed II. None of the differences between the devices under evaluation and the predicate devices will cause the new system to deliver different therapy or significantly different clinical outcomes in the relevant critical performance measures.

Clinical investigations	**☒ Yes ☐ No**
Clinical trial/study protocol, results and analysis provided?	☒ Yes ☐ No Comments:
Pre-market or post-market clinical investigations for subject device?	☐ Pre-market ☒ Post-market ☐ Nil
Randomised controlled trial	☐ Device ☐ Predicate ☒ Nil Comments:
Single-arm trial	☐ Device ☒ Predicate ☐ Nil Comments: s.47 [redacted]

	s.47 [redacted]
Other	☐ Device ☐ Predicate ☐ Nil Comments:

Literature review ☒ **Yes** ☐ **No**

Literature review including search protocol & search results provided?	☒ Yes ☐ No
Literature review scope	☐ Device ☒ Predicate ☐ Similar marketed
Comments	Search through to Oct 2021, with 25 articles included for analysis (CER, p.72-92) Summary from CER (p.118):

Evidence from published literature during the current evaluation period (01 April 2016 to 31 October 2021) are described in the *Medtronic Implantable Programmable Infusion System Scientific Literature Review* (NDHF1463-211733). One recent publication provides current evidence of flow rate accuracy. In the study by Farid et al.,[22] the infused volume accuracy indicated that the SynchroMed II pump delivered drug at a rate slightly lower than predicted but remained within the manufacturer specifications throughout the entire lifespan of the pump, regardless of the concentration of baclofen used.

Additional publications reporting on therapeutic effectiveness outcomes (e.g., reduction in pain or spasticity symptoms) provide further support of clinical benefit of continuous intrathecal drug delivery therapy.[18,19,23–26,28–31] Improvement in pain and spasticity outcomes indirectly demonstrates that the implantable programmable infusion system is achieving its intended purpose by enabling the drug to elicit its intended therapeutic effect. The publications of highest methodological quality include two publications from a single randomized controlled trial (OCEBM level 2)[19,18] and four retrospective study designs (OCEBM level 4) [23–25,28] and one prospective study (OCEBM level 4) for severe spasticity;[26] one prospective observational study (OCEBM level 3) for malignant pain;[29] and one multicenter prospective registry study[31] and one single center prospective study design[30] (OCEBM level 3) for non-malignant pain.

Other clinical experience, including post-market data ☒ **Yes** ☐ **No**

World-wide distribution (sales) numbers for device provided?	☐ Yes ☒ No Comments: s.47
Clinical experience data provided?	☒ Yes ☐ No Data through to Oct 2021 – predicate only
Adverse events with complaint rates	☐ Device ☒ Predicate ☐ Nil Most common events: s.47

	s.47 [redacted]
Public adverse event databases	☐ Device ☐ Predicate ☐ Similar marketed ☐ Nil

Recalls (or actions such as market withdrawals, field corrections, safety alerts)	☐ Device ☒ Predicate ☐ Similar marketed ☐ Nil Information matches recall action in Australia regarding motor stall in 2019.
Corrective and preventative actions (CAPAs)	☐ Device ☒ Predicate ☐ Nil
Registry data	☐ Device ☒ Predicate ☐ Similar marketed ☐ Nil Medtronic Product Surveillance Registry (PSR) (CER, p.93-106): • Web-based registry across sites in North America, Europe, and South America • 9,703 patients enrolled to Oct 2021: **Table 26. Primary Treatment Indications** Primary Treatment Indication[a] / Enrolled Patients (%) Pain 7,357 (75.82%) Non-malignant pain 5,661 (58.34%) Malignant pain 1,695 (17.47%) Pain, Not specified 1 (0.01%) Spasticity 2,133 (21.98%) Combination 161 (1.66%) Non-malignant pain & Spasticity 158 (1.63%) Non-malignant pain & Chemotherapy 2 (0.02%) Malignant pain & Spasticity 1 (0.01%) Not Specified[b] 52 (0.54%) Total Patients 9,703 (100%) [a] For approved indications refer to product labeling for your geography. [b] Includes incomplete data forms at the time of the data snapshot and exited patients where indication was never provided. • Collected events (with or without returned products) were sorted into two categories: product performance events and non-product performance events. • Total of 2,325 product performance events occurred in 1,511 (15.6%) of patients, which is 18% of all events. • 526 (22.6%) of the 2,325 product performance events were related to the pump and 1,596 (68.6%) to the catheter • By far the most common pump issue (189 cases) was motor stall. Design changes were introduced in 2016 and 2017 to reduce the likelihood of non-recoverable stalls. • Overall, there were 2,537 patient deaths – none were attributed by the manufacturer to product performance. • The IFU claims a service life of about 5 years. The registry data estimates 97.2% survival of the SynchroMed II pump when used on-label at 5 years and 89.7% survival at 81 months.
Other	☐ Device ☒ Predicate ☐ Similar marketed ☐ Nil Type of data: SynchroMed II European Post Market Clinical Follow-Up Addendum (CER, p.107):

	• To provide long-term performance data up to 4 years follow-up, measuring flow-rate accuracy. • 15 sites via Medtronic's PSR platform (as above) • n=209 total, with 118 subjects remaining active a 2-years follow-up • Mean pump accuracy ratio of 0.975 [0.833 -1.143 95% confidence interval] observed based on 253 evaluable refills at 2-year follow up (18 to 24 months).
Comments	

Risk management

Risk management documents were not requested for this preliminary review.

Safety in Magnetic Resonance (MR) environment

☒ Active implant ☐ Passive implant ☐ Not implantable

There is an ongoing recall action regarding the effects of MRI exposure on the predicate device – see under heading *Substantial equivalence claim*, above.

Conclusions and recommendations

Reviewer's conclusion and recommendation

This application is for Medtronic's implantable SynchroMed III Programmable Pump Model 8667, which is part of an intrathecal infusion system for the delivery of morphine and baclofen. It is intended to be be used >30 days and up to about 5 years.

In the CER it is stated that the SynchroMed III Programmable Pump will replace the Model 8637 SynchroMed II pump, which was first CE-marked in 2003. The SynchroMed II pump has been included in the ARTG since 2003 and has been the subject of a number of recall actions and safety alerts, including one about MRI that is currently ongoing and not yet agreed with the sponsor.

The new SynchroMed III Programmable Pump obtained EU MDR certification from TUV SUD in Oct 2023 and US FDA approval via PMA supplement in Jun 2023.

Compared to the predicate, the SynchroMed III pump contains a new hybrid assembly with new integrated circuits (ICs), updated software and security and new storage conditions. Both pumps use the same drug delivery catheter models, and refill and catheter access port kits. There are current variation applications underway for the current ARTG inclusions for the Clinician Programmer Application A810 and patient A820 myPTM App used with both pumps, with changes that allow the new pump to work with these apps. These variation applications have not been referred to DCES at this time.

The CER, dated Feb 2023, is for the SychroMed III and new clinical and patient apps. In relation to the SychroMed III, it includes a summary of the pre-clinical design verification and validation testing undertaken, including electrical, mechanical, firmware, telemetry, MR compatibility, biocompatibility, sterilisation, packaging, and usability engineering aspects. From a clinical evidence perspective, there is a claim of equivalence to the SynchroMed II pump with data for this predicate from the manufacturer's post-market clinical study, published literature, and the post-market setting, including from surveillance, Medtronic's Product Surveillance Registry and a PMCF registry study. There is no direct clinical evidence for the subject device.

Sign-Off – Clinical Section Reviewer

Name	[redacted]		
Signature	Signed electronically in TRIM	Date	30 November 2023

Senior Medical Advisor's comments

The application for Medtronic's implantable SynchroMed III Programmable Pump Model 8667 is reliant on claims of substantial equivalence to the predicate, SynchroMed II device. This predicate device has had a history of recall actions and safety alerts, and post-market data provided appears to be dated.

It is recommended that a detailed clinical assessment be conducted focusing on the claims of equivalence and recent post-market clinical evidence.

The applicant should be requested to provide updated post-market experience for both the subject and predicate devices (including sales, as well as "devices remaining in use", as available).

Sign-Off – A/G Senior Medical Advisor

Name	[redacted]		
Signature	Signed electronically in TRIM	Date	1 December 2023

Clinical review Round 2

Information provided in response to questions from previous round of review	*To be completed by DAS: document title and TRIM reference*

Comments

Reviewer's conclusion and recommendation

Sign-Off – Clinical Section Reviewer

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Senior Medical Advisor's comments

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3667495	New FORM	[redacted]	13 Jan 2021

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DAS FORM 2.2.a	Medical device application without an audit assessment checklist		
Comes under	DAS WI 2.2 Preliminary assessment of new non-IVD MD application		
Applicable to	Devices Applications Section	Authorised by	[redacted] Director, DAS
Date issued	28 June 2023	Version #	1.1

Application Details

Submission ID	DA-2023-08940-1
Application ID	DV-2023-DA-32797-1
TRIM Reference	E23-355088
Sponsor Name	Medtronic Australasia Pty Ltd
Manufacturer Name:	MEDTRONIC INC
UPI/Sponsor's reference	Synchromed III 8667
Classification	III
GMDN Term & Code	Intrathecal implantable infusion pump, programmable [46024]

Outcome of the assessment/recommendation:

☐ Seek advice from the delegate

☐ Application has failed preliminary assessment

☐ Sponsor requested to withdraw application

☐ Decision to include kind of device in ARTG according to S41FF

☐ Impose conditions under S41FO

☒ Select application for audit under S41FH

☒ I confirm that I have the appropriate delegation under the *Therapeutic Goods Act 1989*

Name	[redacted]		
Signature	*Signed electronically in TRIM*	Date	1 December 2023

Description of the device

Please include images and references to the relevant documents if required

As per the IFU: D23-4078329

The device Description:

Description

The implantable Medtronic Model 8667 SynchroMed™ III programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8667 SynchroMed III programmable pump and a catheter.

The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).

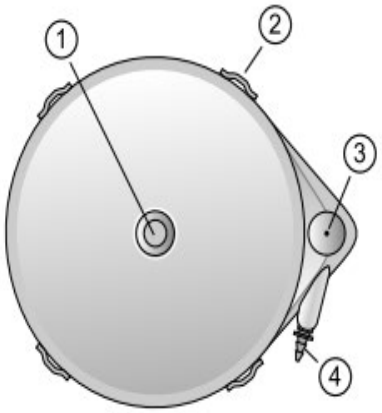


Figure 1. *Pump exterior view.*

① Reservoir fill port
② Suture loop
③ Catheter access port
④ Catheter port

The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the internal pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of prescribed fluid directly into the implanted catheter for drug administration and diagnostic purposes. The prescribed fluid injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit).

The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

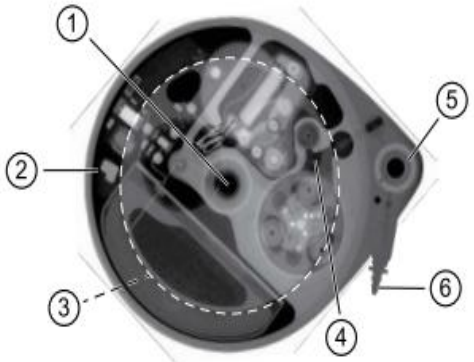


Figure 2. *Pump interior view.*

① Reservoir fill port
② Radiopaque identifier
③ Pump reservoir
④ Internal pump tubing
⑤ Catheter access port
⑥ Catheter port

Part 1 - Application

Information provided in the application – Manufacturer's Evidence	
Manufacturer's Evidence ID	DV-2020-MC-23468-1 Version 5
Conformity assessment document issued by (TGA Conformity Assessment Certificate/Notified body/MDSAP/US FDA/Health Canada/Japan)	EU MD Regulation 2017/745 Annex IX, Chapter I & III
Regulator/Certification Body name and ID	TUV SUD Product Service GmbH Zertifizierstellen
Any relevant information (e.g. is certificate current and if it expired, has it been replaced and when; does the scope of the certificate cover the kind of device/was ME stated correctly, and if it was not, has this information been corrected and when; etc.):  CERTIFICADO ◆ CERTIFICAT EU Quality Management System Certificate (MDR) Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices) No. G12 039709 1291 Rev. 06 Manufacturer: Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA SRN Manufacturer: US-MF-000019977 Authorized Representative: Medtronic B.V. Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS	Manufacturer name: Medtronic Inc Regulation (EU) 2017/745, Annex IX chapter I and III Certificate number: G120397091291 Rev .06 Certificate issue date: 2023-04-06 Certificate expiry date: 2025- 07-02
Does the Notified Body have accreditation to assess the kind of device (under Medical Devices Directive 93/42/EEC and/or Active implantable medical devices 90/385/EEC or MDR 2017/745?	☒ Yes ☐ No Body Name: TÜV SÜD Product Service GmbH Address: Ridlerstraße 65, 80339 MÜNCHEN Country: Germany Phone: +49 (89) 50084261 Fax: +49 (89) 50084230 Email: ps.zert@tuvsud.com Website: http://tuvsud.com/ps Body Number: 0123 Last approval date: 02/08/2023
Any other information if relevant:	Classification: Class III Device Group: J0401 - IMPLANTABLE PUMPS, ELECTRONIC Intended Purpose: -

Preliminary Assessment

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"
Is this medical device one of the kind specified under MD Regulation 4.1 made for the purposes of section 41EA that requires the manufacturer to have a TGA conformity assessment certificate before an application for inclusion of that device in ARTG can be made, and no such certificate is in force? If it is not, provide relevant information below:	☐ Yes ☒ No ☐ N/A
Is application accompanied by the kind of information and in a form determined for the classification of medical device? (Refer Table 2 of the guidance '*Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices*') If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Refer TDAC D23-4078345

◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)
No. G70 039709 1396 Rev. 01

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer - US-MF-000019977

Authorized Representative: Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Classification: Class III
Device Group: J0401 - IMPLANTABLE PUMPS, ELECTRONIC
Basic UDI-DI: 0763000B000197693
Intended Purpose: The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.
Device(s): SynchroMed™ III

Model No. 8667

Model Variant 8667-20
Model Variant 8667-40

Paragraph 41FD(f) – Have the appropriate conformity assessment procedure or requirements, comparable to the conformity assessment procedure been applied to the kind of device? If not, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Preliminary assessment	N/A means 'Not application and/or "not enough information to be assessed"
Paragraph 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures/ comparable procedures, or have procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that information can be obtained from the manufacturer within the period specified in the regulations? If it is not, provide relevant information below:	☒ Yes ☐ No ☐ N/A
Is the device in the application a medical device used for a special purpose (according to Regulation 3.10), e.g. procedure pack? If so, provide relevant information below:	☒ Yes ☐ No ☐ N/A

Part 2 – Application Assessment

Application Assessment	N/A means 'Not application and/or "not enough information to be assessed"
Was the application made for a kind of device?	☒ Yes ☐ No ☐ N/A
Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)? Provide any relevant information below:	☒ Yes ☐ No ☐ N/A

Intrathecal implantable infusion pump, programmable[46024](TGA code table)

Implantable intrathecal infusion pump, programmable [46024](GMDN agency)

A battery-powered, programmable, sterile device designed to be implanted in a patient for the storing and subarachnoid (intrathecal) administration of narcotics/drugs (e.g., morphine sulfate, baclofen) to manage intractable pain and muscle spasms of malignant or non-malignant origin. This implantable infusion pump (IIP) delivers drug doses from its implanted reservoir which is controlled by drug concentration and/or by radio-frequency (RF) signals from an external programming device. The drug reservoir, usually implanted under the skin of the lower abdomen, is typically connected to a catheter placed into the spinal fluid space.

For Class III, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind? If the UPI does not appear to be correct, provide relevant information (including if it has been amended/corrected in the application, or if other application is required, etc.) below:	☒ Yes ☐ No ☐ N/A

Synchromed III 8667

For Class III, are the variants stated in the application correct according to the information provided? If the variants do not appear to be correct, provide relevant information below	☒ Yes ☐ No ☐ N/A

Product Details	
Unique Product Identifier (UPI):	Synchromed III 8667
Total number of devices covered:	2

Variant List

#	Variant type	Variant range
1.	Model number (see guidance docs)	8667-20
2.	Model number (see guidance docs)	8667-40
3.	Gauge (mm)	24 (0.55)
4.	Gauge (mm)	22 (0.7)

Refer TDAC D23-4078345

Application Assessment	N/A means 'Not application and/or "not enough information to be assessed"
Does the intended purpose stated in the application appear to be correct? Does it indicate any concerns? Is it consistent with the GMDN code selected in the application? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A
As per the application Refer D23-4091968 The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. As per IFU: D23-4078329 **Intended purpose** The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.	
Are there any other information/device product characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc.)? Are the device characteristics consistent with the intended purpose of the kind of device, GMDN code selected in then application, etc.? If no, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A

Application Assessment	N/A means 'Not application and/or "not enough information to be assessed"

Device Product Characteristics

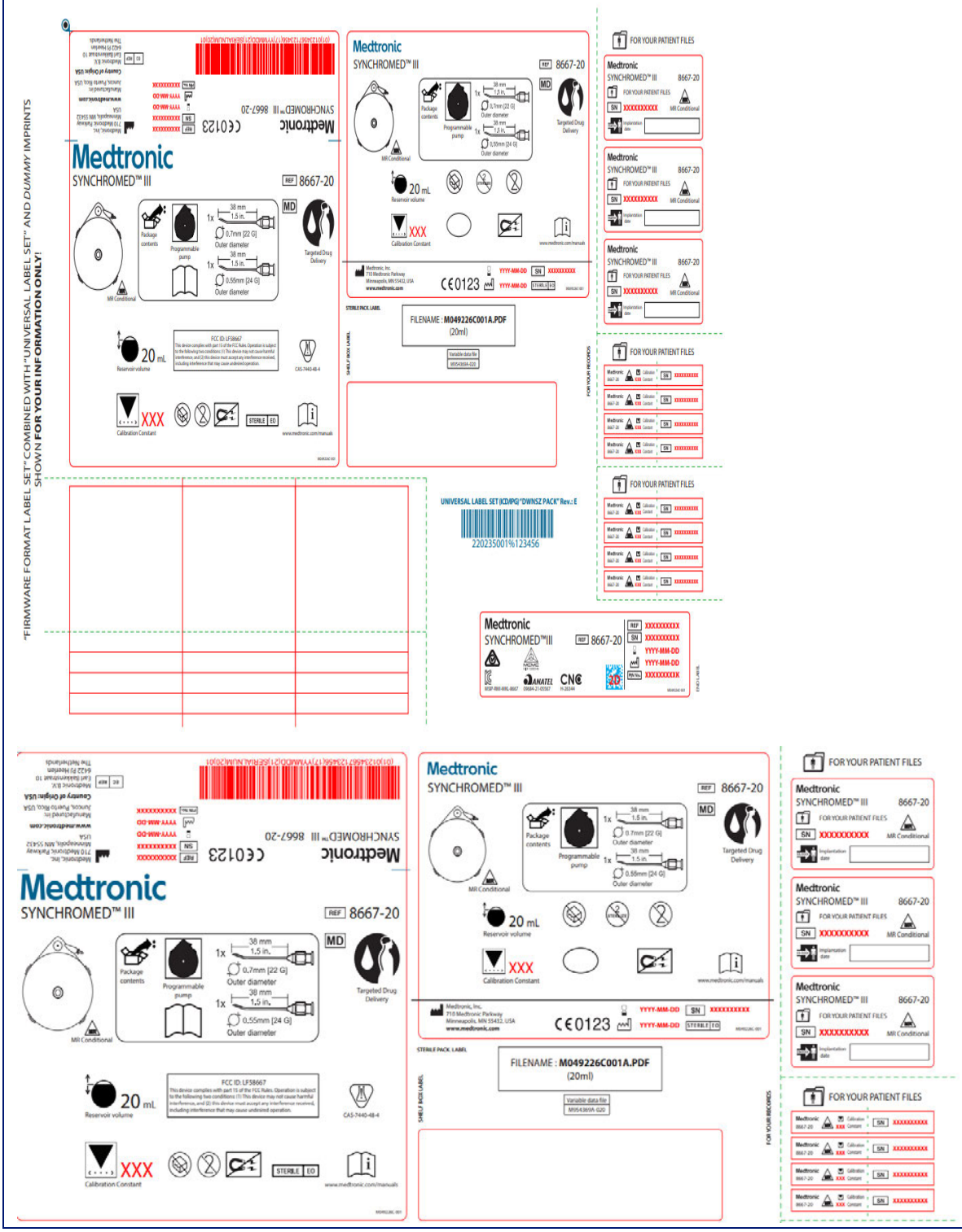
Is the device, or any form of the device, supplied sterile:	Yes
Sterilisation Method:	
Is the device intended to be invasive:	Yes
s the device, or any form of the device, intended for single use:	Yes
Is the device an active device:	Yes
Does the device contain material or ingredients of microbial origin:	No
Does the device contain material or ingredients of recombinant origin:	No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	No
Does the device contain material or ingredients of Human Origin:	No
Does the device contain Human Blood or its components:	
Does the device consist of:	Products packaged as a procedure pack
Does the device contain material or ingredients of Animal Origin rendered non-viable	
Animal Species:	
Country of Origin:	
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:	No
Is the device medicated:	
Is the device formulated:	
Does the product contain a medicine that is supplied separately in the Australian Market	
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:	
Does the device contain a metal on metal bearing:	
I declare that this device contains only components that are medical devices which have been individually certified.	No
Is this a Class IIb spinal fusion device:	
Is the device software:	Yes

The following obligations for software products were acknowledged and certified by the sponsor at the time of application:
The product has been developed to ensure the product can safely perform as intended
Risks have been identified and eliminated or appropriately reduced
The product is resilient to interactions that could result in the unsafe performance of the device
The product provides appropriate safety warnings
The product allows the user to verify that the device is operating correctly

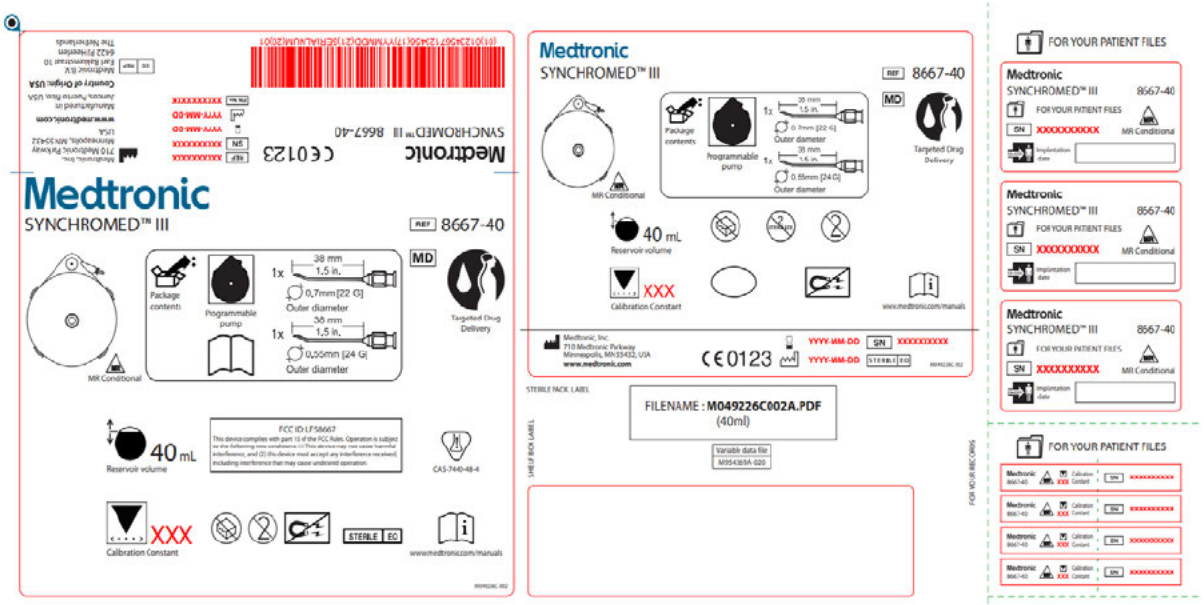
Are there any known concerns about the device (specifically or in general) such as the device is a vaginal mesh or EC Certificate was issued by a notified body of concern, e.g. withdrawal from the MDD accreditation). Refer "Hot Topics" R16/869138 Provide relevant information below:	☐ Yes ☐ No ☒ N/A

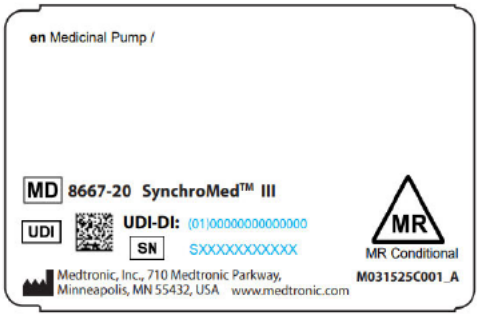
Information attached with the application	
Was any other information provided with the application? If yes, specify and provide relevant information below:	☒ Yes ☐ No ☐ N/A
IFU – D23-4078329 &D23-4078313 TDAC - D23-4078345 TDAR- D23-4078341 CER - D23-4078338 Label - D23-4078334, D23-4078199 Cover letter- D23-4078354 PIL- D23-4078213 s.47	
Declaration of Conformity [Provide the TRIM link] Is the Declaration of Conformity made in accordance to the appropriate Part of Schedule 3 of the MD Regulations and the scope covers the Device? Provide relevant information below:	☐ Yes ☐ No ☒ N/A
Labelling for the medical device [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and13.3? Provide relevant information below	☒ Yes ☐ No ☐ N/A

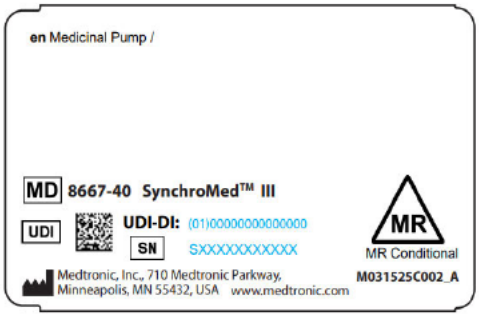
Refer: D23-4078334, D23-4078199



Information attached with the application







The labels are compliant with the EP 13.2 and 13.3.

Instructions for use (IFU) [Provide the TRIM link] Does the IFU comply with EP 13.2 (location) and13.4? Provide relevant information below:	☒ Yes ☐ No ☐ N/A
Refer IFU: D23-4078329 &D23-4078313 The IFU is compliant to EP 13.2 and 13.4.	
Any other information (e.g. data from the National Joint Replacement Registry). Provide relevant information below:	☐ Yes ☒ No ☐ N/A
Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?	☒ Yes ☐ No ☐ N/A

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

Assessor's Name		Position Level	
Signature	*Signed electronically in TRIM*	Date	Click or tap to enter a date.

Reviewers Recommendation

To be completed by an EL1 when the decision delegate is an EL2.

Recommendation	
Pass Preliminary Assessment **Note:** If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☐ Yes ☐ No
Include Kind of Device in ARTG	☐ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☐ No
Other: Procedure following audits – state in the notice reasons for the recommendation	☐ Yes ☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

Assessment against AFF Risk Factors:	
RF 1.1 Device classification	What is the classification of the device? Class III Was the device correctly classified? Yes

	What classification rule does this device have? Click or tap here to enter text.
RF 1.2 Intended purpose	The intended purpose was sufficiently similar between the application intended purpose, CER, IFU and notified body certification.
RF 1.3 Discrepancies in applications	There was no discrepancies in the application
RF 1.4 Regulatory reforms	The current device is not undergoing regulatory reforms
RF 1.5 Regulatory history	Is the device novel? No Is there similar devices on the ARTG? Yes SynchroMed II Programmable Pump – ARTG 389968 – start date 10/6/2022. (ARTG 97770 for Class AIMD from 2003, then 389968 for Class III from 2022) SynchroMed II Clinician Programmer Application A810 – ARTG 308884 – start date 31/08/2018. A820 myPTM App: ARTG 358090, start date 2021. The above A810 and A820 (E23-320291 & E23-320402) undergoing ARTG VA. These apps have been updated to allow use with the SynchroMed III, and to add a new workflow for Refill Only use cases, updated alerts, updated descriptions of myPTM app controls, and an updated name for the A810 to SynchroMed Clinician Programmer Application. Synchromed III 8667, A820 myPTM App (ARTG 358090), & SynchroMed II Clinician Programmer Application A810 (ARTG 308884) share same CER. Clinical advice - Considering that they share the same CER and the outcome of the preliminary assessment (which recommended a focus on claims of equivalence and post-market history), it is feasible to "add" the variation applications to the evaluation of the Synchromed III 8667 (submission ID DA-2023-08940-1) Have any of these kinds of devices from the manufacturer been withdrawn or rejected? No Does the device have TGA conformity assessment certification? No Is the application claiming substantial equivalence? Yes If yes, list the ARTG entries the device claims substantial equivalence SynchroMed II Programmable Pump – ARTG 389968 – Predicate device There are apparently no biological or clinical differences between the devices.

	In relation to clinical equivalency, following is stated (CER, p.55): The SynchroMed III system will be used for the same clinical conditions, same patient population, for the same kind of user. The SynchroMed III system will be used with the same drugs as the SynchroMed II system. The SynchroMed III pump will be implanted in the same site in the body using the same techniques as SynchroMed II. None of the differences between the devices under evaluation and the predicate devices will cause the new system to deliver different therapy or significantly different clinical outcomes in the relevant critical performance measures. Was a search performed for overseas regulatory conformity assessment documents representing product assessment? Yes If yes, include the html links to the searches. AccessGUDID - DEVICE: SYNCHROMED™ III (00763000597030) (nih.gov)
RF 1.6 Regulatory pathway	EU MDR
RF 2	Is there post market signals? No If yes, what kind of device does this pertain to? Choose an item.
RF 3	Is there manufacturer concerns? No If yes, the following manufacturer was identified Choose an item.
Comments	The SynchroMed II pump has been included in the ARTG since 2003 and has been the subject of a number of recall actions and safety alerts, including one about MRI that is currently ongoing and not yet agreed with the sponsor. As SynchroMed III pump showcases substantial equivalence with the predicate device which holds post market history, it is considered to select the device for further review.
Outcome/ Action	Select for Level 2 audit
Decision date	15/7/24
Assessor	[redacted]

Assessor's Name		Position Level	
Signature	*Signed electronically in TRIM*	Date	Click or tap to enter a date.

Delegate's Checklist and Decision

Delegate's Checklist		
Do you have delegation for the purposes of section 41FDB of the Act (*Preliminary assessment* of applications)?	☐ Yes	☐ No
Do you have delegation for the purposes of section 41FF if application is finalised without the audit?	☐ Yes	☐ No
Have you checked that all requirements set out under section 41FF have been considered and met in making this decision?	☐ Yes	☐ No
Specify other if required: section 41FO	☐ Yes	☐ No
Other: section 41FL	☐ Yes	☐ No

Delegate's Decision		
Pass Preliminary Assessment **Note:** If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☐ Yes	☐ No
Include Kind of Device in ARTG	☐ Yes	☐ No
Impose Conditions under section 41FO of the Act	☐ Yes	☐ No
Other: section 41FL	☐ Yes	☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

Assessor's Name		Position Level	
Signature	*Signed electronically in TRIM*	Date	Click or tap to enter a date.

Version History

Version	TRIM Reference	Description of change	Authors	Effective date
V1.0	D23-5062537	New FORM Previously issued as DAS FORM 4.a Version 1.0 (D19-5922185). Re-issued as Version 1.0	[redacted]	1 May 2023
V1.1	D23-5427683	Minor change in terminology - Labelling has been changed to IFU and EP 13.3 to 13.4 Reference to AIMD removed as devices re-classified to Class III	[redacted]	28 Jun 2023

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

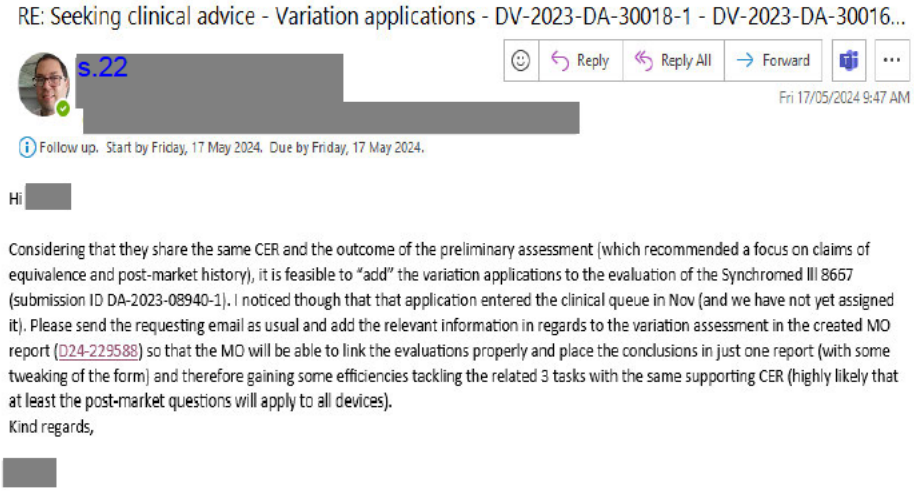
Internal Form			
DCS FORM 1.a	Application Audit Clinical Assessment Report		
Comes under	DCDS SOP 1 Clinical assessment of application audit		
Applicable to	Devices Clinical Section	Authorised by	s.22 Director and Principal Medical Advisor, DCS
Date issued	13 January 2021	Version #	1.0

Application details

To be completed by Clinical Section Reviewer

Submission ID	DA-2023-08940-1 DA-2023-08222-1 (Variation application) DA-2023-08221-1 (Variation application)
Application ID	DV-2023-DA-32797-1 DV-2023-DA-30018-1 (Variation application) DV-2023-DA-30016-1 (Variation application)
Sponsor name	Medtronic Australasia Pty Ltd
Manufacturer name	Medtronic Inc 710 Medtronic Parkway Minneapolis MN 55432 United States Of America
Device classification	Class III
GMDN code and term	Intrathecal implantable infusion pump, programmable[46024]
Name of device(s)	Synchromed III 8667

Submission TRIM reference	E23-355088 E23-320402 (Variation application) E23-320291 (Variation application)
Comments	See preliminary review: D23-4084599 **Comments regarding variation applications:** DCR/VA team has two variation applications under review for ARTG's 358090 & 308884. The device in ARTG 358090 is a A820 myPTM App and ARTG 308884 is a SynchroMed II Clinician Programmer Application A810. The variation request is to change IP, FD, and UPI. It appears that the updates in ARTG's 358090 & 308884 is to accommodate new hardware Synchromed III 8667 which is yet to be registered in the ARTG entry. Clinical advice was sought from s.22 for these variation applications and [redacted] has advised to add the relevant information regarding the variation assessment in this report. Please refer to clinical advice – D24-1966100



RE: Seeking clinical advice - Variation applications - DV-2023-DA-30018-1 - DV-2023-DA-30016...

Reply | Reply All | Forward

s.22 [redacted]

Fri 17/05/2024 9:47 AM

Follow up. Start by Friday, 17 May 2024. Due by Friday, 17 May 2024.

Hi [redacted]

Considering that they share the same CER and the outcome of the preliminary assessment (which recommended a focus on claims of equivalence and post-market history), it is feasible to "add" the variation applications to the evaluation of the Synchromed III 8667 (submission ID DA-2023-08940-1). I noticed though that that application entered the clinical queue in Nov (and we have not yet assigned it). Please send the requesting email as usual and add the relevant information in regards to the variation assessment in the created MO report (D24-229588) so that the MO will be able to link the evaluations properly and place the conclusions in just one report (with some tweaking of the form) and therefore gaining some efficiencies tackling the related 3 tasks with the same supporting CER (highly likely that at least the post-market questions will apply to all devices).

Kind regards,

[redacted]

Device description

To be completed by Clinical Section Reviewer.

Information provided for the application – labels, IFU, advertising, CER etc.

Clinical Reviewer to complete. If there are multiple applications or devices in the submission, add and complete a table for each application or device.

UPI	Synchromed III 8667

Device description

From Pump manual:

Intended purpose

The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.

…

Description

The implantable Medtronic Model 8667 SynchroMed™ III programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8667 SynchroMed III programmable pump and a catheter.

The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).

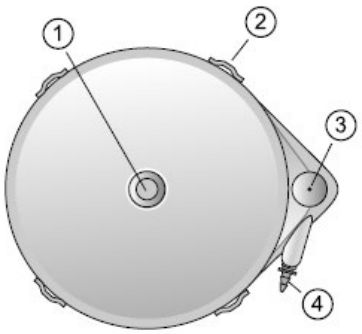


Figure 1. *Pump exterior view.*

① Reservoir fill port
② Suture loop
③ Catheter access port
④ Catheter port

The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the internal pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of prescribed fluid directly into the implanted catheter for drug administration and diagnostic purposes. The prescribed fluid injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit).

The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

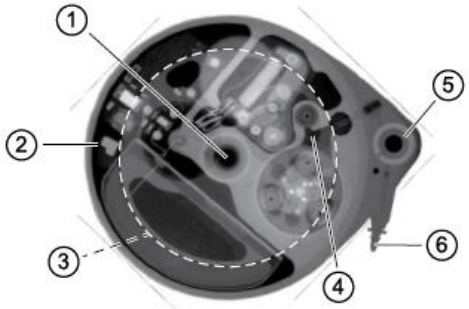


Figure 2. *Pump interior view.*

① Reservoir fill port
② Radiopaque identifier
③ Pump reservoir
④ Internal pump tubing
⑤ Catheter access port
⑥ Catheter port

...

Device specifications

Table 1. Shipping and operating values for the Model 8667 SynchroMed III pump

	Shipping	Operating
Fluid in reservoir	Sterile water	—
Shipping flow rate	0.006 mL/day	—
Infusion modes	Minimum rate	Single bolus Priming bolus Bridge bolus Simple continuous Flex Minimum rate Stopped pump
Alarms		
Critical alarm	Disabled	Enabled with an interval programmed
Non-critical alarm	Disabled	Enabled with an interval programmed

Table 2. Device specifications for the Model 8667 SynchroMed III pump[a]

	8667-20	8667-40
Pump		
Thickness (including septum)	19.6 mm	26.1 mm
Weight (empty/full)	146/166 g	152/192 g
Displacement volume	88 mL	118 mL
Diameter (including CAP)	87.5 mm	87.5 mm
Pump reservoir		
Volume	20.0 mL	40.0 mL
Residual volume	1.4 mL	1.4 mL
Fill volume at shipping from manufacturing	17.5 mL	37.5 mL
Reservoir fill port		
Septum puncture life	500 punctures	500 punctures
Catheter access port		
Septum puncture life	100 punctures	100 punctures
Flow rate		
Maximum programmable[b]	24 mL/day	24 mL/day
Minimum programmable[b]	0.048 mL/day	0.048 mL/day
Stopped pump maximum leakage	0.030 mL/day	0.030 mL/day
Bacterial retentive filter		
Pore size	0.22 µm (micron)	0.22 µm (micron)
Power source		
Battery	Lithium / carbon monofluoride - silver vanadium oxide	Lithium / carbon monofluoride - silver vanadium oxide
Longevity	Rate dependent (Figure 3)	Rate dependent (Figure 3)
Radiopaque identifier	NFY	NFY

Table 2. Device specifications for the Model 8667 SynchroMed III pump[a] (continued)

	8667-20	8667-40
Reservoir pressure	20.68 kPa to 34.75 kPa	20.68 kPa to 34.75 kPa
Expected lifetime	The pump has a service life of at least five (5) years operation up to a 0.910 mL/day flow rate from the day of implant until it reaches end of service.	The pump has a service life of at least five (5) years operation up to a 0.910 mL/day flow rate from the day of implant until it reaches end of service.

[a] All measurements are approximate.

[b] Actual limits depend on pump calibration constant and selected infusion mode.

The pump is implanted in a subcutaneous pocket in the lower abdomen.

For use in adult and pediatric patients, for >30 days.

From the Reference manual, the following drugs can be used with the pump:

	Table 1. Medtronic implantable infusion systems are approved for use with the following drugs

Infusion System is specifically approved for[a]	SynchroMed II	SynchroMed III	IsoMed
Preservative-free morphine sulfate sterile solution **The maximum approved concentration is 25 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate sterile solution.	X	X	X
Preservative-free morphine hydrochloride sterile solution **The maximum approved concentration is 25 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of preservative-free morphine hydrochloride sterile solution.	X	X	X
Preservative-free ziconotide solution for injection **The maximum approved concentration is 100 µg/mL.** A 0.9% solution of preservative-free sodium chloride injection can only be used with preservative-free ziconotide sterile solution after the initial fill of the pump with this drug.	X	X	—
Baclofen injection **The maximum approved concentration is 2 mg/mL.** A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of baclofen injection.	X	X	X

[a] Refer to the appropriate drug labeling for a complete list of indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.
X Specific pump is approved for use with drug.
— Specific pump is not approved for use with drug.

Device configurations & variants	Variants: 20mL and 40mL pump reservoir volumes
System or procedure pack	From IFU: **Package contents** ▪ Pump ▪ Needle, 22-gauge (black sheath) ▪ Needle, 24-gauge (purple sheath) ▪ Product literature ▪ Registration form ▪ Patient identification card SynchroMed III Programmable Infusion System consists of: • SynchroMed III programmable pump • intrathecal catheter • refill kit – used to refill pump reservoir through refill septum • catheter access port (CAP) kit • wireless clinician programmer

	• Personal Therapy Manager (which include communicators) – allows patient to activate delivery of physician programmed supplemental bolus doses of drug. • software Under this table is a diagram of the entire system.
Accessories or compatible devices	See above
Comments	

Note: ***Unique product identifier (UPI)*** is only relevant for Class III/AIMD devices as it forms part of the "kind of medical device" by which these devices are entered in the ARTG. The UPI is given to the device by its manufacturer to identify the device and any variants. **Device name** is relevant to devices other than Class III/AIMD. For non-Class III/AIMD devices, the name of the device does not form part of the "kind of medical device" and is not recorded in the ARTG entry.

Scope of assessment

The aim of this assessment is to verify whether Synchromed lll 8667 complies with essential principles (EPs) 1, 2, 3, 4, 6, 13 and 14 from a clinical perspective.

Assessment

Clinical evidence report (CER)

Competency of CER author	s.22 meets the criteria.
Comments	*Comment on whether the CER includes evaluation of the clinical data.*

Demonstration of equivalence ☒ **Yes** ☐ **No**

Comparator device	SynchroMed II implantable drug delivery system, comprised of theModel 8637 pump and Model A810/A820 therapy apps
Can the comparator device be considered substantially equivalent to the subject device based on clinical, technical and biological aspects?	☐ Yes ☐ No Comments: Differences are described in Table 11 of the CER. Assertions that these will make no difference to the safety or performance appear reasonable, with the patient and clinician interfaces predominating, along with cybersecurity enhancements. The basis for these assertions appears reasonable. Accuracy has been validated against the predicate device (CER, section 5.2.1.1); Biological equivalence is justified on the basis of the usage of the

	same kinds of materials contacting the body and drugs it is intended to administer. Clinical equivalence is justified where there are minor differences. Equivalence claims are acceptable.

Manufacturer's clinical investigations

Has the manufacturer conducted clinical investigations?	☒ Yes ☐ No If no, what is the rationale and is this acceptable? *Comment on rationale and its acceptability*
Pre-market or post-market clinical investigations?	☐ Pre-market ☒ Post-market
Randomised controlled trial	☐ Device ☐ Predicate ☐ Nil Comments: *Include details of trial and outcomes*
Single-arm trial	☐ Device ☒ Predicate ☐ Nil Comments: detailed in D23-4084599
Other	☐ Device ☒ Predicate ☐ Nil Comments: Post market surveillance registry
Investigation scope and design	As per D23-4084599. This appears reasonable in establishing the safety and performance profile of the device.

Clinical literature review ☐ **Yes** ☐ **No**

Literature search protocol provided	☒ Yes ☐ No Comments: discussed in D23-4084599
Selection criteria of the literature review	☐ Device ☒ Predicate ☐ Similar marketed ☐ Addresses all device variants (if any) in the device application ☐ Addresses the same clinical condition
Literature type	☒ Published literature ☐ Unpublished literature ☐ Other

Data appraisal	Detailed in Appendix F. Methods appear appropriate, but literature search period covers a short period.

Other clinical experience ☒ **Yes** ☐ **No**

Adverse events with complaint rates	☐ Device ☒ Predicate ☐ Nil Comment: complaints relatively rare and are consistent with expectations for device of this intended usage.
Public adverse event databases	☐ Device ☒ Predicate ☐ Similar marketed ☐ Nil Comment: *Describe data/information and any significant issues.*
Recalls (or actions such as market withdrawals, field corrections, safety alerts)	☒ Device ☒ Predicate ☐ Similar marketed ☐ Nil Comment: PSUR for period 1/11/22 – 31/10/23 section 4.5 states no new Field Safety Corrective actions initiated in the period or period of previous report, with no new or emerging information affecting benefit-risk determination
Corrective and preventative actions (CAPAs)	☒ Device ☒ Predicate ☐ Nil Comment: As per section 4.4 of PSUR. 5 open actions, all of which have been deemed not to represent a new hazard or require an update to risk management file in 4 cases, with one, regarding function of the Synchromed II device in Telemetry Mode, which resulted in updates to risk management files but did not introduce a new hazard or affect the benefit- risk determination.
Registry data	☐ Device ☒ Predicate ☐ Similar marketed ☐ Nil Comment: *Describe data/information and any significant issues.*
Other	☐ Device ☐ Predicate ☐ Similar marketed ☐ Nil Comment: *Describe data/information and any significant issues.*
Comments	*Comment on any issues with the clinical experience data/information*

Risk management

From a clinical perspective, does the report/FMEA include the risks arising from the use of the device	☐ Yes ☐ No Comments: not reviewed

for its intended purpose, and foreseeable misuse of the device?	
Do the risks associated with the use of the device appear to have been adequately mitigated?	☐ Yes ☐ No Comments: *Comment if risks not adequately mitigated*
Are the residual risks appropriately documented in the IFU/labels/PIL?	☐ Yes ☐ No Comments: *Comment if residual risks not appropriately documented*

Safety in Magnetic Resonance (MR) environment

☒ Active implant ☐ Passive implant ☐ Not implantable

MR safety labelling claim	MR Conditional If MR Conditional, specified conditions of use: Not reviewed – stated to be detailed in the “MRI guidelines for Medtronic implantable infusion systems manual” in the information for prescribers. Unable to locate this document or information in the Synchromed III Implant manual
Overall, does the evidence provided support the MR safety claims in the IFU/labels/PIL?	☐ Yes ☐ No Comments: *Consider the following: clinical data to confirm computer modelling capability of manufacturer (or: any similar devices approved by FDA for similar MR conditions/claims); image artefact dimensions, acceptance criteria, wanings and precautions in IFU/labels/PIL, hazards considered in risk management documents.*

IFU, labels and other information provided with the device

From a clinical perspective, does the information provided with the device (IFU, labels, PIL, etc.) provide adequate information on the intended purpose, proper use, and warnings about risks to patients and users?	☒ Yes ☐ No Comments: *Comment on whether IFU etc contains appropriate information on the use of the device, appropriate contraindications, warnings, precautions, and complications consistent with the clinical evidence provided.*

Assessment summary

Application is for an intrathecal pump that appears to be an iterative development from the manufacturer's own predicate. Claims of equivalence appear substantiated and are accepted. MRI claims have not been reviewed, but there is no reason to necessitate this, considering equivalence to a predicate device with many years of use.

Conclusions and recommendations

Clinical assessor's conclusion and recommendation

Based on assessment of the information provided for this application audit, the Synchromed lll 8667 complies with essential principles 1, 3, 4, 6, 13 and 14 from a clinical perspective.

Sign-Off – Senior Medical Advisor

Name	[redacted]		
Signature	Signed electronically in TRIM	Date	2 September 2024

Clinical review Round 2

Information provided in response to questions from previous round of assessment	*To be completed by DAS: document title and TRIM reference*

Comments

Include summary assessment of the information provided in response to questions from the previous round of clinical assessment.

Detail any issues with the clinical data or IFU/labels/PIL in relation to the safety and performance of the device. Issues should be detailed in terms of compliance with the applicable essential principle(s).

Clinical assessor's conclusion and recommendation

Following assessment of the information provided for this application audit in relation to the *UPI/Device Name*, it is recommended that the sponsor be requested to provide the following:

1.

OR

Based on assessment of the information provided for this application audit, the *UPI/Device Name* complies with essential principles 1, 2, 3, 4, 6, 13 and 14 from a clinical perspective.

OR

It is recommended that *UPI/Device Name* be considered for referral to ACMD.

OR

Based on assessment of the information provided for this application audit, the *UPI/Device Name* does not comply with essential principles *Enter EP numbers here* from a clinical perspective.

Provide reasons if it is concluded that there is non-compliance with an EP

IF NECESSARY

It is recommended that the following condition be imposed (under s41FO of the *Therapeutic Goods Act*) if *UPI/Device Name* is included in the ARTG

•

Sign-Off – Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Senior Medical Advisor's comments

Sign-Off – Senior Medical Advisor

Name			
Signature	Signed electronically in TRIM	Date	Click or tap to enter a date.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3667497	New FORM	[redacted]	13 Jan 2021

Appendix 1 – Documentation provided by the sponsor

To be completed by Clinical Section Reviewer

Type of documentation	Document name, version number/reference & date	TRIM location
Labels		
IFU		
Patient information leaflet (PIL)		
Patient information card (PIC)		
Advertising		
Clinical evaluation report (CER)		
CV of clinical expert		
Risk management report		
FMEA		
MRI information		
(Other documents)		

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DRMS FORM 9.b	Audit Checklist – Single Device		
Comes under	DRMS SOP 9 Performing an Application Audit		
Applicable to	Devices Review Management Section	Authorised by	s.22 A/g Director, DRMS
Date issued	31 May 2024	Version #	1.2

Ensure you are able to view hidden text when using this form

Instruction to Assessors

- Complete a separate checklist for each submission ID.
- The white blank boxes below the questions are to record comments and concerns.
- If there are no comments or concerns, delete the box.
- Do not make any comments or notes in grey coloured boxes. Either use the white blank boxes below or the adjacent white boxes with Yes/No drop downs.
- Add further table rows as required by clicking on the blue cross on the bottom right corner of the Device 1 rows.
- Remove tables and rows that are not needed or do not apply.

Level 2

Application Details

Submission ID:	DA-2023-08940-1
Application ID	DV-2023-DA-32797-1
TRIM folder	E23-355088
Sponsor Name:	Medtronic Australasia Pty Ltd
Manufacturer Name:	MEDTRONIC INC (United States Of America)[9913]
Unique Product Identifier (UPI)	Synchromed lll 8667
Classification	Class III
GMDN Term and Code	Intrathecal implantable infusion pump, programmable[46024]

Document 6

Recommendation to the Delegate

Include Kind of Device in ARTG

Description

Description

The implantable Medtronic Model 8667 SynchroMed™ III programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8667 SynchroMed III programmable pump and a catheter.

The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).

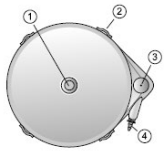


Figure 1. Pump exterior view.

① Reservoir fill port
② Suture loop
③ Catheter access port
④ Catheter port

The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the internal pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of prescribed fluid directly into the implanted catheter for drug administration and diagnostic purposes. The prescribed fluid injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit).

The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

Intended purpose

The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.

Package contents

- Pump
- Needle, 22-gauge (black sheath)
- Needle, 24-gauge (purple sheath)
- Product literature
- Registration form
- Patient identification card

IFU: D23-4078329

Part 1 Preliminary Assessment

Has the application has passed *preliminary assessment* under s41FDB?	YES
s41FDB(2)(a): Is the application made in accordance with the form and manner approved for the classification of medical device?	YES
s41FDB(2)(d): Is the application accompanied by the kind of information and in a form determined for the classification of medical device?	YES

Part 2 Selection for Audit

Under what section was the application selected for audit?	s41FH(1) (b)
If selected under s41FH(b) state reasons:	
Information to be provided: 1. Please provide updated post-market experience/report for both the subject and predicate devices (including sales, as well as "devices remaining in use", as available)	
Date of s41FH selection notice	1/12/2023
TRIM Reference to s41FH selection notice	D23-4361689 attached pdf

Part 3 Conformity Assessment Documents

Paragraphs 41FD(f) and (g): Have the appropriate conformity assessment procedure or requirements, comparable to the conformity assessment procedure been applied to the kind of device?	YES
Is the device in the application a medical device used for a special purpose (according to Regulation 3.10), e.g., procedure pack under Clause 7.5?	NO
Manufacturer's Evidence *(QMS Certificate)*	
Manufacturer's Evidence ID	DV-2020-MC-23468-1 (D24-3737549)
Conformity assessment document details	
Manufacturer's Name:	Medtronic Inc (United States Of America)[9913]
Manufacturer's Address:	710 Medtronic Parkway Minneapolis MN 55432 United States Of America S [92255]
Certificate No.:	G12 039709 1291 Rev 09
Issued by:	TUV SUD Product Service GmbH Zertifizierstellen [0123]
Issued under:	MDR Annex IX, Chapter I & III
Expiry date:	02/07/2025
Does the Regulator/Certification Body have accreditation to assess the kind of device?	YES

ERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1291 Rev. 09

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer - US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

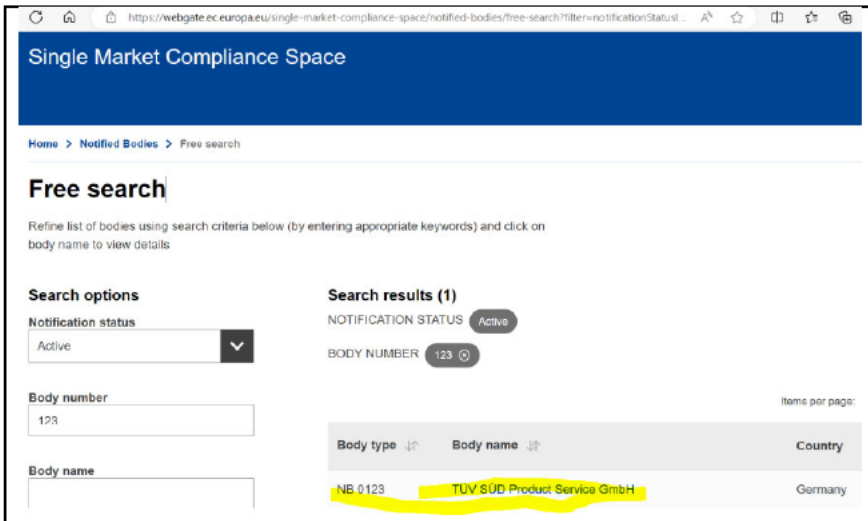
The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 039709 1291 Rev. 09

Report No.:	713329460
Preceding Certificate No.:	G12 039709 1291 Rev. 08
Valid from:	2024-03-15
Valid until:	2025-07-02
Date of Initial Issuance:	2020-07-03

s.22

Issue date: 2024-03-15

Ref: D24-3737549



Does the scope of the certificate cover the Device?	YES

Classification: Class III
Device Group: J0401 - IMPLANTABLE PUMPS, ELECTRONIC
Intended Purpose: -

Ref: D24-3737549

Evidence of Product Assessment

Has evidence of product assessment been provided?	YES

Product assessment document details

Manufacturer's Name:	Medtronic Inc (United States Of America)[9913]
Manufacturer's Address:	710 Medtronic Parkway Minneapolis MN 55432 United States Of America S [92255]
Certificate No.:	**No. G70 039709 1396 Rev. 01**
Issued by:	TUV SUD Product Service GmbH Zertifizierstellen [0123]
Issued under:	Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
Expiry date:	21/06/2027
Does the scope of the product assessment document cover the Device?	YES

Ref: TDAC D23-4078345

◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1396 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer - US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s)
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G70 039709 1396 Rev. 01

Report No.: 713265568

Preceding Certificate No.: G70 039709 1396 Rev. 00

Valid from: 2023-10-27
Valid until: 2027-06-21

Date of Initial Issuance: 2022-06-22

s.22

Issue date: 2023-10-27

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www.zlg.de
BS-MDR-099

TÜV SÜD
Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1396 Rev. 01

Classification:	Class III
Device Group:	J0401 - IMPLANTABLE PUMPS, ELECTRONIC
Basic UDI-DI:	0763000B00003397Q
Intended Purpose:	The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.
Device(s):	SynchroMed™ II
	Model No. 8637
	Model Variant 8637-20
	Model Variant 8637-40
Classification:	Class III
Device Group:	J0401 - IMPLANTABLE PUMPS, ELECTRONIC
Basic UDI-DI:	0763000B00197693
Intended Purpose:	The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.
Device(s):	SynchroMed™ III
	Model No. 8667
	Model Variant 8667-20
	Model Variant 8667-40

Manufacturer's Declaration of Conformity (DoC)	
Has a DoC, that is compliant with Schedule 3 of the Regulations, been provided? •	N/A
Not requested and it is a non-mandatory audit.	
Does the declaration identify the kind of device in the application?	N/A

Part 4 Audit Assessment

Assessment of the certifications made under section 41FD of *the Therapeutic Goods Act 1989*

4.1 Application Information

Medical Device – Paragraph 41FD(a)	
Is the product in the application a medical device according to section 41BD of the Act?	YES
Intended purpose – Paragraph 41FD(b)	
Are devices of the kind intended to be used for a purpose as ascertained under subsection 41BD(2)?	YES
Intended purpose stated in the application:	
The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site	
Is the intended purpose consistent with manufacturer's documentation provided?	YES

Intended purpose

The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site.

IFU: D23-4078329

Functional Description – Class III	
Functional description as stated in the application:	
The implantable programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a pump and a catheter. The catheter connects to the pump catheter port. The kit contains a drug infusion pump and two needles.	
Is the functional description consistent with the information stated in the IFU and/or the CER and/or the surgical technique?	YES

Description

The implantable Medtronic Model 8667 SynchroMed™ III programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8667 SynchroMed III programmable pump and a catheter.

The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).

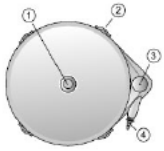


Figure 1. Pump exterior view.

① Reservoir fill port
② Suture loop
③ Catheter access port
④ Catheter port

The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the internal pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of prescribed fluid directly into the implanted catheter for drug administration and diagnostic purposes. The prescribed fluid injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit).

The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

IFU – D23-4078329

Preliminary note from clinical reviewer: *the present assessment will cover SynchroMed III 8667 programmable pump (class III, implantable) and updates to applications SynchroMed Clinician Programmer-A810 and myPTM App-A820 (both class III, non-implantable) that were made to allow compatibility with the new pump.*

Overview of the system

Medtronic's SynchroMed III programmable pump and components of the infusion system are used in the management of medical conditions that require chronic infusion of drugs to the intrathecal space. These medical conditions include chronic malignant and nonmalignant pain and severe spasticity of spinal or cerebral origin.

The SynchroMed III Programmable Infusion System consists of the SynchroMed III programmable pump, intrathecal catheter, refill kit, catheter access port (CAP) kit, clinician programmer and Personal Therapy Manager (which include communicators) and software. The implantable programmable pump along with the implantable catheter store and deliver a prescribed drug to a specific site [...] The clinician programmer is used by the clinician to wirelessly communicate with the infusion pump to program therapy settings to the device. The Personal Therapy Manager may be provided to allow the patient to activate delivery of physician programmed supplemental bolus doses of drug [...]

for use in adult and pediatric populations in accordance with approved drug labeling [...]

Table 6: SynchroMed III Implantable Infusion System is Approved for Use with the Following Drugs

SynchroMed III is specifically approved for[a]
Preservative-free morphine sulfate sterile solution The maximum approved concentration is 25 mg/mL. A 0.9% solution of preservative-free sodium chloride injection can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate sterile solution.
Preservative-free morphine hydrochloride sterile solution

CEAR-D23-4078338

Global Medical Device Nomenclature (GMDN)

Is the GMDN the relevant preferred term for the devices of the kind (Regulation 1.7) and consistent with the intended purpose?	YES

GMDN term and code as stated in application:

Intrathecal implantable infusion pump, programmable[46024]

GMDN Code Description:

Name Implantable intrathecal infusion pump, programmable

Definition A battery-powered programmable device designed to be implanted in a patient for the storing and subarachnoid (intrathecal) administration of narcotics/drugs (e.g., morphine sulfate, baclofen) to manage intractable pain and muscle spasms of malignant or non-malignant origin. This implantable infusion pump (IIP) delivers drug doses from its implanted refillable reservoir which is controlled by drug concentration and/or by radio-frequency (RF) signals from an external programming device. The drug reservoir, usually implanted under the skin of the lower abdomen, is typically connected to a catheter placed into the spinal fluid space.

Code 46024

Status Active

Term Details - GMDN Members (gmdnagency.org)

Unique Product Identifier (UPI) – Class III

Does the UPI stated in the application accurately identify the device(s) of the kind?	YES

UPI Comparison Table

UPI in application	UPI in Product assessment:	UPI in DoC:	UPI in Labels:	UPI in IFU:
Synchromed III 8667	SynchroMed™ III Model No. 8667 Model Variant 8667-20 Model Variant 8667-40	N/A	Medtronic SYNCHROMED™ III Medtronic SYNCHROMED™ III 8667-40	Medtronic SynchroMed™ III Programmable pump

Total number of devices and variants – Class III

Are the variants stated in the application correct according to the information provided?	YES

Total no. of devices stated in application:	
2	
Variants stated in application:	

Variant List

#	Variant type	Variant range
1.	Model number (see guidance docs)	8667-20
2.	Model number (see guidance docs)	8667-40
3.	Gauge (mm)	24 (0.55)
4.	Gauge (mm)	22 (0.7)

Device product characteristics

Are the device characteristics in the application consistent with the manufacturer's information?	YES

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes
Is the device intended to be invasive: Yes
Is the device, or any form of the device, intended for single use: Yes
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device consist of: Products packaged as a procedure pack
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable: No
Is the device software or does it incorporate software: Yes

Does the device contain medicines or materials of animal, microbial, recombinant, or human origin?	NO
For devices containing medicines and/or materials of animal, recombinant, or microbial origin, please specify which categories are applicable to each device and whether the devices are compliant with relevant EPs.	

Classification – Paragraph 41FD(c)

Is the kind of device correctly classified according to the classification rules for medical devices (Division 3.1 and Schedule 2 of the MD Regulations)?	YES

Class III as per Rule 3.4(4)(e).

3.4 Surgically invasive medical devices intended for long-term use and implantable medical devices

(1) This clause applies to:
(a) a surgically invasive medical device that is intended for long-term use; and
(b) an implantable medical device.

(2) Subject to subclauses (3), (4), (4A) and (4B), the device is classified as Class IIb.

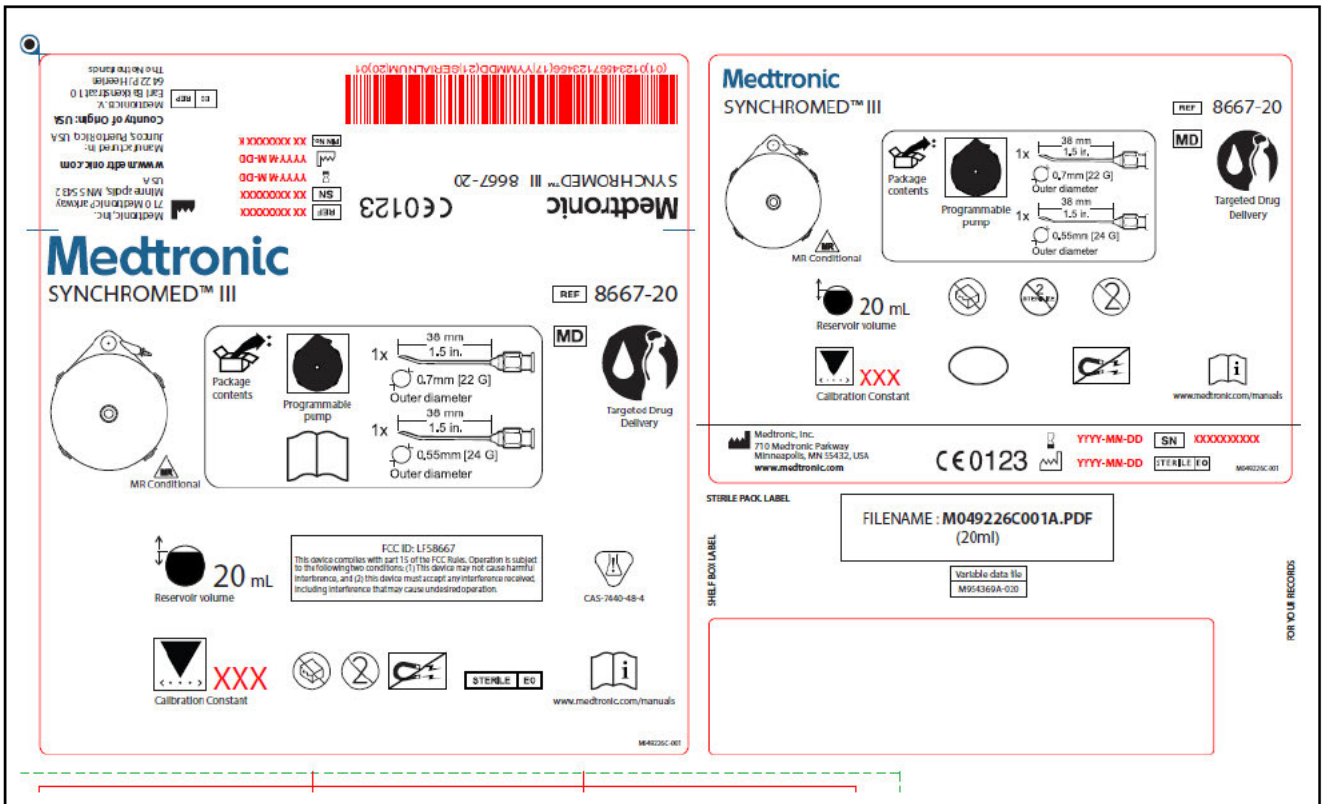
(3) If the device is intended by the manufacturer to be placed in the teeth of a patient, the device is classified as Class IIa.

(4) If the device is intended by the manufacturer:
(a) to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient; or
(b) to have a biological effect; or
(c) to be wholly, or mostly, absorbed by a patient's body; or
(d) to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or
(e) to be used to administer medicine;
the device is classified as Class III.

Kinds of Medical Devices – Section 41BE	
Is the application made for a kind of medical device?	YES

4.2 Essential Principles (Schedule 1 of the MD Regulations)

Paragraphs 41FD(d) and (e) – Do the devices of the kind comply with the essential principles?	YES
Essential Principle 13 – Information to be provided with medical devices	
Has sufficient information been provided to demonstrate compliance with Essential Principle 13?	YES
Do the label(s) comply with EP 13.2 (location) and 13.3?	YES



D23-4078334

EP 13.3 Checklist

EP 13.3 Item	Compliant?
1. The manufacturer's name, or trading name, and address	YES
2. The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)	YES
3. Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging	YES
4. Any particular handling or storage requirements applying to the device	N/A
5. Any warnings, restrictions, or precautions that should be taken, in relation to use of the device	YES
6. Any special operating instructions for the use of the device	YES
7. If applicable, an indication that the device is intended for a single use only	YES

EP 13.3 Item	Compliant?
8. If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional	N/A
9. If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only	N/A
10. For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device	YES
11. The batch code, lot number or serial number of the device	YES
12. If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used	YES
13. If the information provided with the device does not include the information mentioned in item 12—a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)	N/A
14. If applicable, the words 'for export only'	N/A
Yes	
Does the IFU comply with EP 13.2 (location) and 13.4?	YES
Refer IFU: D23-4078329 &D23-4078313 Additional information (D24-3932734) regarding assessor's concern (D24-3932828) on the warnings, MRI and other risks associated with the device was addressed by the sponsor and the assessor determined the explanation is acceptable to comply EP 13.4.	

EP 13.3 Item	Compliant?
2. Further information requires to comply with EP 13.4: The instructions for use (IFU) must comply all applicable items of with EP 13.4. Currently, items 3, 4 and 5 are missing in your provided IFUs. Note: Your SynchroMed™ Infusion system patient manual provided detailed warnings and issues around your device, but the IFU does not contain the similar information and it is inconsistent. You may consider adding similar information in your IFU to comply the EP. **Medtronic's Response** The assessor mentions "the *IFU does not contain the similar information* and it is inconsistent. *You may consider adding similar information in your IFU to comply the EP.*"	

EP 13.3 Item	Compliant?

The information for prescribers manual (IFU) supplied as document ***7 . M961343A063A_IFP*** in the eBS/tBS online application provides information about contraindication warnings precautions, adverse events similar to those listed in the Synchromed Infusion System Patient Manual.

Information on, drug stability and emergency procedures is included in the Health Care Professional Reference provided with the eBS/tBS online application as document **8. M961294A065A_IDSEP**

The information in both the physician and patient manuals is consistent, however, the language used differs to accommodate the specific needs of the target audience i.e. Healthcare professional and patient.

The table below details of the sections within the IFUs supplied with the device where information described as missing can be located, compared to the requirements set out in EP13.4, items 3, 4 and 5.

Evidence of EP 13.4. items 3, 4 and 5 in Instructions for Use		
3	Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices).	Refer to document provided with the initial eBS/tBS online application ***7 . M961343A063A_IFP*** SynchroMed™ IsoMed Implantable infusion systems - Information for prescribers Refer to Sections titled: • Warnings, • Precautions • Appendix: Electromagnetic interference
4	Information about the intended performance of the device and any undesirable side effects caused by use of the device.	Refer to documents provided with the initial eBS/tBS online application **7 . M961343A063A_IFP** SynchroMed™ IsoMed Implantable infusion systems - Information for prescribers Refer to Section: Adverse events Summary **8. M961294A065A_IDSEP** Indications, drug stability, and emergency procedures SynchroMedTM and IsoMed implantable infusion systems
5	Any contra indications, warnings, restrictions, or precautions that may apply in relation to use of the device.	Refer to documents provided with the initial eBS/tBS online application **7 . M961343A063A_IFP**

EP 13.3 Item	Compliant?

		SynchroMed™ IsoMed Implantable infusion systems – Information for prescribers **See sections:** Contraindications Warnings Precautions **8. M961294A065A_IDSEP** Indications, drug stability, and emergency procedures SynchroMedTM and IsoMed implantable infusion systems

Additionally, MRI manual is also provided to the assessor. Over a telephone conversation with the sponsor on 11 September 2024, sponsor confirmed that all the information provided with the application would be provided to the customer and the patient with the device. Therefore, no additional concerns.

Medtronic

MRI guidelines for Medtronic implantable infusion systems

8667
8637
8472

Directrices sobre RM para sistemas de infusión implantables de Medtronic

- Clinician programmer and communicator

Table 1. MRI scan-type eligibility

Pump	MRI equipment	Possible scan locations
SynchroMed II: 8637-20, 8637-40 SynchroMed III: 8667-20, 8667-40	1.5-T or 3-T	Entire body (head, torso, extremities)

MRI information for Model 8637-20 and 8637-40 SynchroMed™ II pumps and Model 8667-20 and 8667-40 SynchroMed III pumps

MR Conditional: If the patient is implanted with a Medtronic SynchroMed II or SynchroMed III pump, MRI examinations of the entire body may be safely performed under the following conditions:

- 1.5-Tesla (T) and 3-T horizontal cylindrical system for hydrogen imaging
- Radio-frequency (RF) coil: Any type
- Maximum spatial field gradient of 19T/m (1900 gauss/cm)
- Maximum gradient slew rate: 200 T/m/s or less per axis
- Maximum RF field intensity: First Level Controlled Operating Mode
- Active scan time: The risk of heating increases for active torso scanning durations over 30 minutes

SynchroMed II and SynchroMed III pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Safety and diagnostic issues

- **Tissue heating adjacent to implant during MRI scans**
  Heating—Presence of the pump can potentially cause an increase of local temperatures in tissues near the pump. Active torso scanning durations exceeding 30 minutes increase the risk of heating. If the patient indicates discomfort at any time during an MRI, the MRI procedures should be stopped or the intensity (ie, gradient, RF) of the scan sequence should be reduced. Following the MRI recommendations in this manual will minimize risk of tissue heating.
- **Peripheral nerve stimulation during MRI scans**
  Time-varying gradient magnetic fields—Presence of the pump may potentially cause an increase of the induced electric field in tissues near the pump. In the event that the patient reports stimulation during the scan, the proper procedure is the same as for patients without implants—stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.
- **Static magnetic field**
  The patient may experience a slight tugging sensation at the pump implant site. An elastic garment or wrap may prevent the pump from moving and reduce the sensation the patient may experience.

Ref: D24-3861067 2.01 M994068A037A_MRI Guideli..

EP 13.4 Checklist

EP 13.4 Item	Compliant?
1. The manufacturer's name, or trading name, and address	YES
2. The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used	YES
3. Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)	YES
4. Information about the intended performance of the device and any undesirable side effects caused by use of the device	YES
5. Any contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device	YES
6. Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging	YES
7. Any particular handling or storage requirements applying to the device	N/A
8. If applicable, an indication that the device is intended for a single use only	YES
9. If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional	N/A
10. If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device—the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device—the device is intended for performance evaluation only	N/A
11. For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device	YES
12. For a device that is intended by the manufacturer to be supplied in a sterile state: (a) an indication that the device is sterile; and (b) information about what to do if sterile packaging is damaged; and (c) if appropriate, instructions for resterilisation of the device	YES

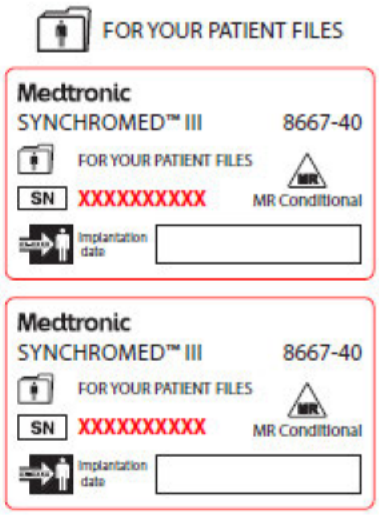
EP 13.4 Item	Compliant?
13. For a medical device that is intended by the manufacturer to be sterilised before use—instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles	N/A
14. Any special operating instructions for the use of the device	YES
15. Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life	YES
16. Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life	YES
17. Information about any treatment or handling needed before the device can be used	YES
18. For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose—sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination	YES
19. For an implantable medical device—information about any risks associated with its implantation	YES
20. For a reusable device: (a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging and, if appropriate, resterilisation of the device); and (b) an indication of the number of times the device may be safely reused	N/A
21. For a medical device that is intended by the manufacturer to emit radiation for medical purposes—details of the nature, type, intensity and distribution of the radiation emitted	N/A
22. Information about precautions that should be taken by a patient and the user if the performance of the device changes	YES
23. Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions	YES

EP 13.4 Item	Compliant?
24. Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device	YES
25. Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device	YES
25A. For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device	N/A
26. Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device	YES
27. Information about the degree of accuracy claimed if the device has a measuring function	N/A
28. Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device	YES

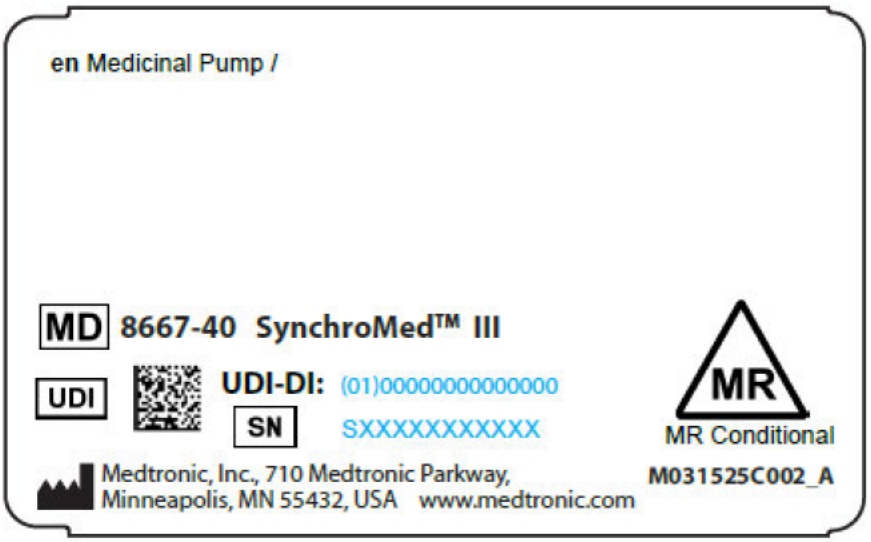
EP 13.4 Item	Compliant?
29. For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only); (d) assay procedure including calculations and interpretation of results; (e) interfering substances and their effect on the performance of the assay; (f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision; (g) clinical performance characteristics, such as sensitivity and specificity; (h) reference intervals, if appropriate; (i) any precautions to be taken in relation to substances or materials that present a risk of infection	N/A
30. For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles	N/A
31. For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles	N/A

EP 13A.2 Checklist

Does the Patient Implant Card comply with EP 13A.2?	YES



D23-4078334: PIC label



D23-4078199: PIC card template

EP 13A.2 Item	Compliant?
1. (a) the name of the device; and (b) the model of the device; and (c) the batch code, lot number or serial number of the device	YES
2. The manufacturer's name, address and website	YES

EP 13A.3 Checklist

EP 13A.3 Item	Compliant?
Does the Patient Information Leaflet comply with EP 13A.3?	YES

D24-3861067

1.02 M961287A056A_color_PTG

1.03 PIL M030463C_a_002_view

D24-3861067

> Medtronic complies with the EP13A.3 requirement for a Patient Information Leaflet through a two-leaflet strategy. The regulations do not mandate that this information be provided in a single leaflet.
>
> This two-leaflet strategy is explained in the **TGA Letter for PIL labelling**, was included as Document 9 in the initial eBS application and as **Attachment 1.01** for ease of reference.
>
> To meet EP 13A.3, the following documents are provided:
> - **Patient Therapy Guide** - Document 10 (M961287A056A_color_PTG) in the initial online eBS application, also provided as **Attachment 1.02** for easy reference.
> - **PIL Document** - Provided as Attachment 11 (PIL M030463C_a_002_view) in the initial online application and as **Attachment 1.03** again for ease of reference
>
> The TGA letter for PIL labelling cross-references the requirements in both documents with those outlined in EP13A.3.

D24-3861067

Additional information/explanation provided by the sponsor complies the EP 13A.3: D24-3932734

EP 13A.3 Item	Compliant?

Information to be provided

1. Further information requires to comply with EP 13A.3:

The Patient Information Leaflet (PIL) must contain all components of EP 13A.3. Currently 1, 4, 5, 6 and 7 of EP 13A.3 are missing, as you did not address TGA requirements properly.

Note: You have not provided any information on how all of the PIL information will be provided to the patients. Proper clarifications on how and what information will be provided to patients to comply the EP.

Medtronic's Response

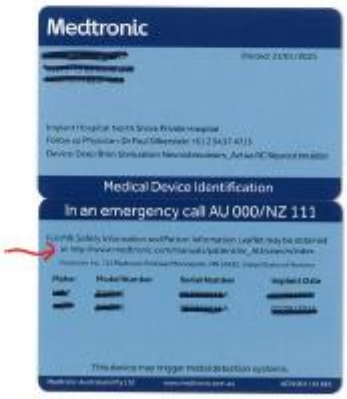
As previously explained in our response to TGA on 6th September 2024, Medtronic complies with the EP13A.3 requirement for a Patient Information Leaflet ***through a two-leaflet strategy***.

This strategy consists of providing the following documents:

- Patient Therapy Guide (PTG) – previously provided to TGA
- Patient Implant Leaflet Document – Previously provided to TGA

This two-leaflet strategy was detailed in our previous response and complies with the regulatory requirements set out in EP13A.3 , which **does not** mandate that a Patient Information Leaflet (PIL) is to be provided as a single document.

- 1, 4, 5, 6 and 7 of EP 13A.3 described by the assessor as missing are included in the Patient Therapy Guide (PTG). Previously provided as **Attachment 1.02**, 6th of September 2024 response to TGA and Attachment 13 of the tBS/eBS online application. Location of the information within the Patient Therapy Guide (PTG) are described below.

EP 13A.3	
EP13A.3	**Evidence of Compliance**
Patient information Leaflet etc. for implantable Devices (1) Either: (a) leaflet (a *patient information leaflet*) that includes the information covered by subclauses (2) and (3) and that satisfies subclause (4) and clause 13A.4 must be made available for provision to the patient concerned; or	TGA Patient Implant Information Leaflet requirements are met by providing two separate leaflets for each patient. The strategy consists of providing: • The patient Implant information (PIL) and Patient Therapy Guide • Patient Therapy Guide (PTG) These documents are made available to patients via the Medtronic Patient Information Library. https://manuals.medtronic.com/manuals/patient/en_AU/search/index Printed copies can also be provided upon request. The address of the e-manual site is listed on the Patient Implant Card (PIC) as shown below. 
(b) information covered by subclauses (2) and (3) that is in electronic form and that satisfies subclause (4) and clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.	
4 (a) the intended performance of the device; and	Refer to the Patient Therapy Guide page 18 -20 Sections titled "Purpose of the Infusion System (indications) and Your Infusion System.

	Page 44-45 - How your infusion system works
4 (b) any undesirable side effects that could be caused by use of the device.	Refer to the Patient Therapy Guide Page 21 - Contraindications (when the infusion system should not be implanted) Pages 21- 35 - Sections Risk and Benefits, Risks of Surgery, Possible System Complications, Warnings
5. Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2).	Refer to the Patient Therapy Guide Page 21 - Contraindications (when the infusion system should not be implanted) Pages 21- 35 - Sections Risk and Benefits , Risks of Surgery, Possible System Complications , Warnings
6 (a) warnings about risks that could arise from the interaction of the device with other equipment; and	Refer to the Patient Therapy Guide Page 39-40 - Precautions
6 (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional (i) Example 1: The risk of electrical interference from electro-surgical devices. (ii) Example 2: The risk of magnetic field interference from magnetic resonance imaging devices.	Refer to the Patient Therapy Guide Section 5. Appendix Electromagnetic Interference - Page 61 onwards Page 52 onwards - Common Questions
7 (a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and	Refer to page Patient Therapy Guide Page 47 - Recovery from Surgery Page 51 - What to do if you hear an alarm Page 52 - Section Common Questions
7 (b) symptoms that could indicate that the device is malfunctioning; and	Refer to page Patient Therapy Guide Page 49 - When to call your doctor or nurse Page 51 - What to do if you hear an alarm

EP 13A.3 Item		Compliant?
	Various sections of the Patient therapy guide (e.g. page 31) also mention "you should be monitored carefully at each doctor visit for any new neurological signs or symptoms"	
7 (c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and	Refer to page Patient Therapy Guide Page 25 - Elective Replacement Indicator Page 49 - When to call your doctor or nurse	
7 (d) the expected device lifetime; and	Refer to page Patient Therapy Guide Page 52 - Common Questions - How long will the pump battery last	
7 (e) anything that could shorten or lengthen the device lifetime; and	Refer to page Patient Therapy Guide Page 52 - Common Questions - When would the pump or catheter need to be replaced.	
7 (f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and	Refer to page Patient Therapy Guide Page 25 Elective Replacement Indicator	
7 (g) other circumstances in which the patient should contact a health professional in relation to the operation of the device	Refer to page Patient Therapy Guide Page 48 - Follow up Visits. Page 49 When to call your doctor or nurse	
	D24-3932734 Assessor has determined the explanation is acceptable and the device is complaint with the EP 13A.3.	
1. (a) the name of the device; and (b) the model of the device		YES
2. (a) the intended purpose of the device; and (b) the kind of patient on whom the device is intended to be used		YES
3. Any special operating instructions for the use of the device		YES
4. (a) the intended performance of the device; and (b) any undesirable side effects that could be caused by use of the device		YES
5. Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)		YES

EP 13A.3 Item		Compliant?
6.	(a) warnings about risks that could arise from the interaction of the device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional Example 1: The risk of electrical interference from electro-surgical devices. Example 2: The risk of magnetic field interference from magnetic resonance imaging devices.	YES
7.	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and (b) symptoms that could indicate that the device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected device lifetime; and (e) anything that could shorten or lengthen the device lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the device	YES
8.	(a) the materials and substances included in the device; and (b) any manufacturing residuals that could pose a risk to the patient	YES
9.	(a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and (b) the address of the Therapeutic Goods Administration's website	YES
Have MR conditional or MR safe claims been made? Comment below if the claims have been assessed as acceptable.		YES

EP 13A.3 Item	Compliant?

Labels: D23-4078334

Medtronic

MRI guidelines for Medtronic implantable infusion systems

8667
8637
8472

Directrices sobre RM para sistemas de infusión implantables de Medtronic

- Clinician programmer and communicator

Table 1. MRI scan-type eligibility

Pump	MRI equipment	Possible scan locations
SynchroMed II: 8637-20, 8637-40 SynchroMed III: 8667-20, 8667-40	1.5-T or 3-T	Entire body (head, torso, extremities)

MRI information for Model 8637-20 and 8637-40 SynchroMed™ II pumps and Model 8667-20 and 8667-40 SynchroMed III pumps

MR Conditional: If the patient is implanted with a Medtronic SynchroMed II or SynchroMed III pump, MRI examinations of the entire body may be safely performed under the following conditions:

- 1.5-Tesla (T) and 3-T horizontal cylindrical system for hydrogen imaging
- Radio-frequency (RF) coil: Any type
- Maximum spatial field gradient of 19T/m (1900 gauss/cm)
- Maximum gradient slew rate: 200 T/m/s or less per axis
- Maximum RF field intensity: First Level Controlled Operating Mode
- Active scan time: The risk of heating increases for active torso scanning durations over 30 minutes

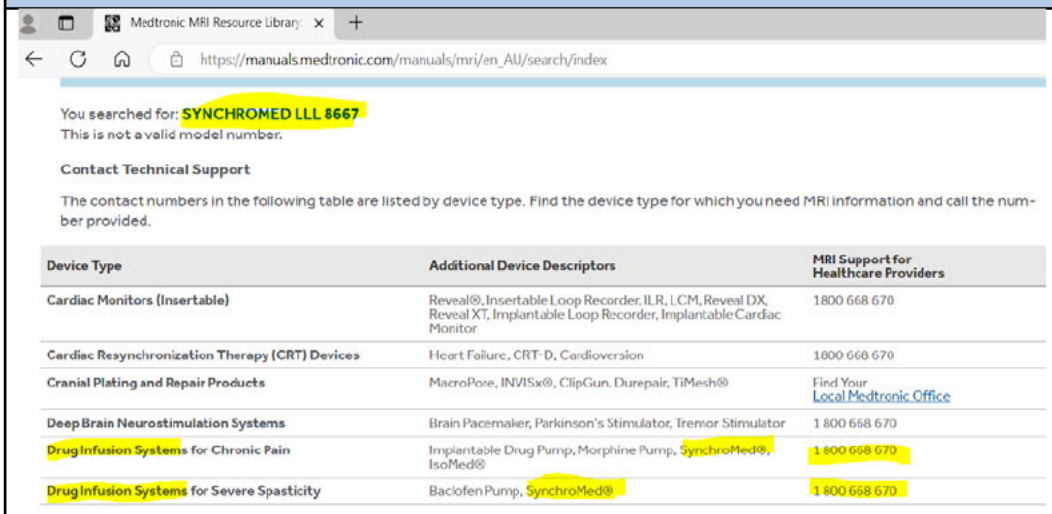
SynchroMed II and SynchroMed III pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Safety and diagnostic issues

- **Tissue heating adjacent to implant during MRI scans**
  Heating—Presence of the pump can potentially cause an increase of local temperatures in tissues near the pump. Active torso scanning durations exceeding 30 minutes increase the risk of heating. If the patient indicates discomfort at any time during an MRI, the MRI procedures should be stopped or the intensity (ie, gradient, RF) of the scan sequence should be reduced. Following the MRI recommendations in this manual will minimize risk of tissue heating.
- **Peripheral nerve stimulation during MRI scans**
  Time-varying gradient magnetic fields—Presence of the pump may potentially cause an increase of the induced electric field in tissues near the pump. In the event that the patient reports stimulation during the scan, the proper procedure is the same as for patients without implants—stop the MRI scan and adjust the scan parameters to reduce the potential for nerve stimulation.
- **Static magnetic field**
  The patient may experience a slight tugging sensation at the pump implant site. An elastic garment or wrap may prevent the pump from moving and reduce the sensation the patient may experience.

Ref: D24-3861067 2.01 M994068A037A_MRI Guideli...

Medtronic referred to the MRI issues of Australia to the Helpline number provided below:

EP 13A.3 Item	Compliant?
 Medtronic MRI Resource Library:	
Medical device software: does the information provided with the Device comply with EP 13B Software—version numbers and build numbers?	YES

EP13B Checklist

EP 13 B Item	Compliant?
1. For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.	YES
2. The current version number and current build number of the software: (a) must be in English; and (b) may also be in any other language	YES

Device label - Version and build number of the software.

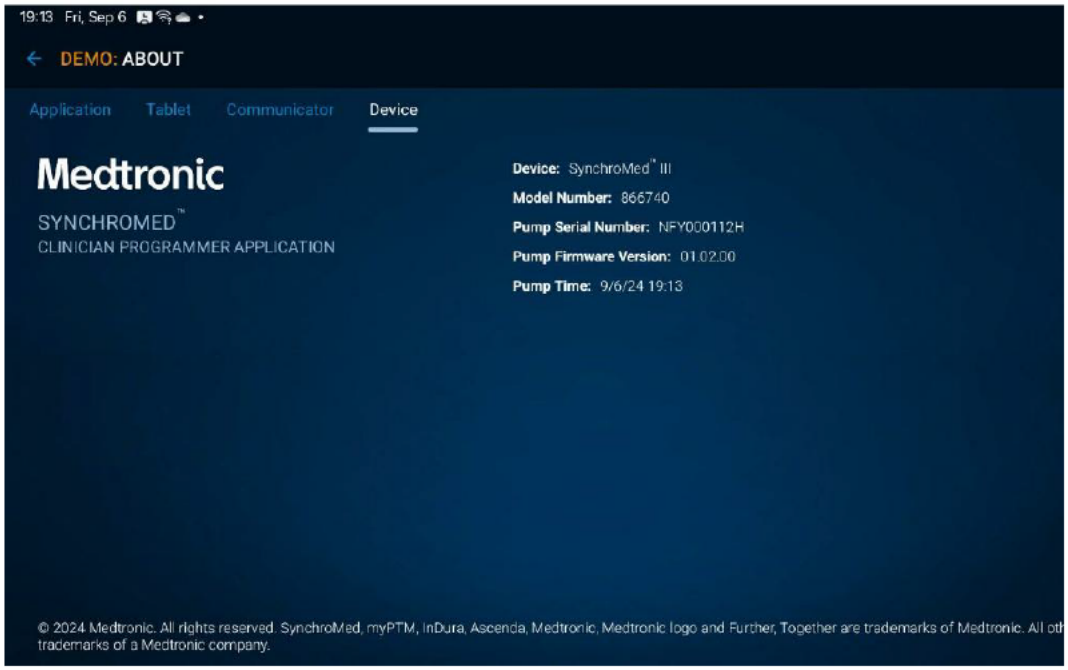
The version and build information for the Synchromed III device is located under the "About" tab in the 810 Clinical Programmer Application software (supplied separately under ARTG 308884).

The version number shown against the "Pump Firmware Version", and the build number are the least significant digits after the Version. Refer to **Attachment 3.01 About Screen (Snapshot)**

- for Synchromed III device where the version is 01.02 and build number is "00"

Medtronic has met EP 13B by:

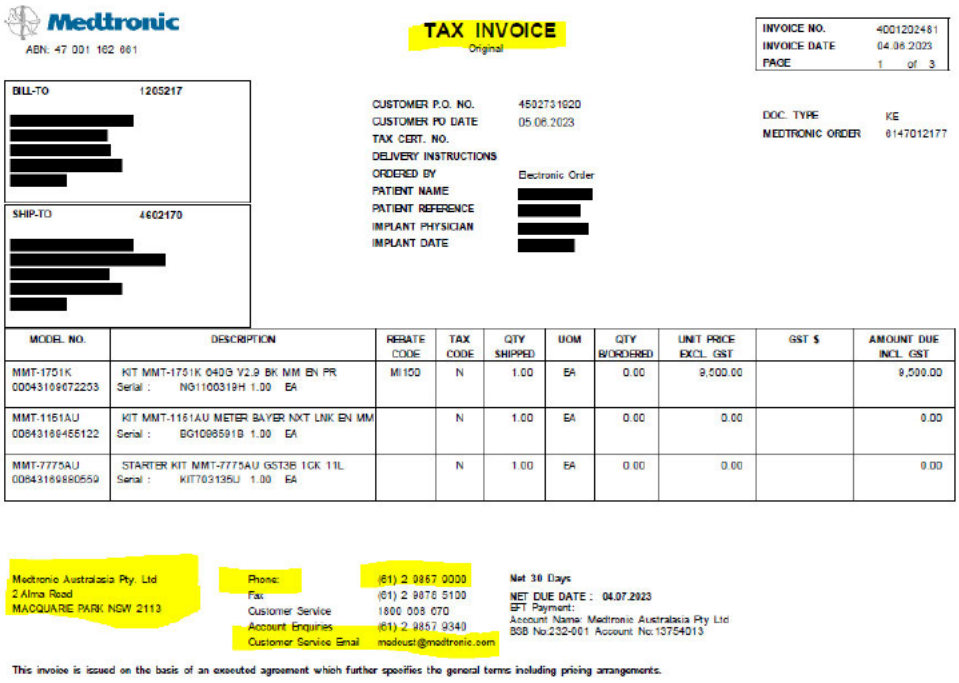
- Version and build Information is accessible i.e. accessed via the About screen in the Clinical Programmer Application and indicated under the heading tab "Device".
- Version and build Information is identifiable – the version and build information is located under the against the "Pump Firmware Version". The version number shown, and the build number are the least significant digits after the Version
  - for Synchromed III device the version is "01.02" and build number is "00"



3.01 About Screen (Snapshot)

Ref: D24-3861067

Regulation 10.2 – Information about the Sponsor	
Has sufficient information been provided to demonstrate compliance with Regulation 10.2?	YES



Medtronic
ABN: 47 001 162 661

TAX INVOICE
Original

INVOICE NO.	4001202481
INVOICE DATE	04.06.2023
PAGE	1 of 3

BILL-TO 1205217
[redacted]

SHIP-TO 4602170
[redacted]

CUSTOMER P.O. NO.	4502731020
CUSTOMER PO DATE	05.06.2023
TAX CERT. NO.	
DELIVERY INSTRUCTIONS	
ORDERED BY	Electronic Order
PATIENT NAME	[redacted]
PATIENT REFERENCE	[redacted]
IMPLANT PHYSICIAN	[redacted]
IMPLANT DATE	[redacted]

DOC. TYPE	KE
MEDTRONIC ORDER	8147012177

MODEL NO.	DESCRIPTION	REBATE CODE	TAX CODE	QTY SHIPPED	UOM	QTY B/ORDERED	UNIT PRICE EXCL. GST	GST $	AMOUNT DUE INCL. GST
MMT-1751K 00643169672253	KIT MMT-1751K 640G V2.9 BK MM EN PR Serial : NG1100319H 1.00 EA	MI100	N	1.00	EA	0.00	9,500.00		9,500.00
MMT-1151AU 00843169455122	KIT MMT-1151AU METER BAYER NXT LNK EN MM Serial : BG1008591B 1.00 EA		N	1.00	EA	0.00	0.00		0.00
MMT-7775AU 00843169880559	STARTER KIT MMT-7775AU GST3B 1CK 11L Serial : KIT703135U 1.00 EA		N	1.00	EA	0.00	0.00		0.00

Medtronic Australasia Pty. Ltd
2 Alma Road
MACQUARIE PARK NSW 2113

Phone:	(61) 2 9857 0000
Fax	(61) 2 9878 5100
Customer Service	1800 668 670
Account Enquiries	(61) 2 9857 9340
Customer Service Email	medaust@medtronic.com

Net 30 Days
NET DUE DATE : 04.07.2023
EFT Payment:
Account Name: Medtronic Australasia Pty Ltd
BSB No:232-001 Account No:13754013

This invoice is issued on the basis of an executed agreement which further specifies the general terms including pricing arrangements.

4.01 Sample SAP Invoice

Ref: D24-3861067

Essential Principle 14 (and conformance with Part 8 of Schedule 3)	
Has sufficient information been provided to demonstrate compliance with Essential Principle 14 and conformance with Part 8 of Schedule 3?	YES
Clinical assessment report status	Complete
Clinical assessment report TRIM	D24-229588

Conclusions and recommendations

Clinical assessor's conclusion and recommendation

Based on assessment of the information provided for this application audit, the Synchromed III 8667 complies with essential principles 1, 3, 4, 6, 13 and 14 from a clinical perspective.

Sign-Off – Senior Medical Advisor

Name	[redacted]		
Signature	Signed electronically in TRIM	Date	2 September 2024

D24-229588

Essential Principle – other	
Has compliance with any other EP been assessed and has sufficient information been provided?	YES
The device is also compliant with essential principles 1, 3, 4, and 6.	

4.3 Other matters

Paragraphs 41FD(h) – Does the submitted information demonstrate compliance with the applicable provisions of the Therapeutic Goods Advertising Code and other requirements (if any) relating to advertising? **Note:** if advertising is only aimed at health professionals these requirements are not applicable.	N/A
Paragraphs 41FD(i) – Do devices of the kind contain substances that are prohibited imports under the Customs Act 1901?	N/A
Paragraphs 41FD(j) – Is the information included in and with the application complete, and correct?	N/A

Part 5 Other assessment

Was any other information provided with the application?	YES
TDAR- D23-4078341	
Has all the requested information been provided?	YES
Are there any other concerns that need to be considered/assessed?	NO
Consent to Supply	
Label	
IFU	
PIC/PIL	
Other	

Assessor's Recommendation

Recommendation
Include Kind of Device in the ARTG?
The matters certified by the sponsor for this medical device application under Section 41FD of the Act are correct. The applicant provided information to substantiate the application of the appropriate conformity assessment procedures and complies the requirements of the s41FH Notice. The device has been correctly classified and complies with the applicable essential principles after multiple communication with the sponsor. Therefore, I recommend the inclusion of the device in the ARTG.
Impose Conditions under section 41FO of the Act? - NO

Assessor Sign-Off

Name	[redacted]		
Position	APS6, DRMS		
Signature	Signed electronically in TRIM.	Date	13 September 2024

Reviewer's Recommendation

If the decision delegate is an EL2, the reviewer's recommendation is to be completed by an EL1.

Recommendation	
Agree with the Assessor's recommendation?	YES

Concerns raised by the assessor regarding the provision of multiple documents to the patient via the PIL were discussed with the sponsor and their justification has been accepted.

The device can be used to deliver different therapies therefore the *decision to provide two Leaflets to the patient, one for the products associated with their system and one for their specific therapy, eliminates the risk of patient confusion and ensures all presented information is pertinent to their condition and indicated therapy.*

The medical device application is appropriate, and the matters certified by the sponsor under Section 41FD of the Act are correct. The Device has been correctly classified, complies with the essential principles and the manufacturer has provided sufficient information to substantiate the application of the appropriate conformity assessment procedures. Nothing further is required, I recommend the application be approved.

Chris Harwood EL1 DRMS signed electronically 12 September 2024

Delegate's Checklist

Do you have current delegation under Section 41FDB of the Act? (*Preliminary assessment of applications*)	YES
Do you have delegation for the purposes of Section 41FI related to auditing of applications (or Section 41FF if application is finalised without audit)? *(Include/not to include the kind of device in the Register)*	YES
Have you checked that all requirements set out under section 41FI (or section 41FF) have been considered and met in making this decision?	YES
Impose conditions under section 41FO?	NO
Specify other if required: section 41FJ (if the decision is not to include the kind of device in the ARTG—state in the notice the reasons for the decision)	NO

Delegate's Decision

Include Kind of Device in the Register? In including the Device in the Register, 41FL (unique device number is assigned) and 41FJ(a) (notify the applicant of decision) is applied.
Yes
Impose Conditions under section 41FO of the Act?

No

Delegate Sign-off

Name	[redacted]		
Position	APS6, DRMS		
Signature	*Signed electronically in TRIM*	Date	13/09/2024

Version History

Version	TRIM Reference	Description of change	Authors	Effective date
V1.0	D24-1463039	Previously issued as DAS FORM 6.a Version 1.3 (D21-3306275) Renumbered and reissued as DRMS FORM 9.b Version 1.0	[redacted]	1 May 2024
V1.1	D24-1897078	Added UPI comparison table for Class III on p.9	[redacted]	17 May 2024
V.1.2	D24-2107412	Added intended purpose stated in the application to section 4.1 of the form	[redacted]	31 May 2024