IVD Applications Without Audit - Completed (Commencing from 25/11/2010)

Application ID	Submission ID	Sponsor	Manufacturer	Class	GMDN	Application Fees Paid	20 Day Decision Date	Assessor assigned	Decision	Date of decision	Date of notification	ARTG ID
DV-2013-IVA-01001-1	DA-2013-00481-1	Immuno Pty Ltd	Nova Tec Immundiagnostica GmbH (Germany)	2	Bacterial infectious disease IVDs[CT353]	23/01/2013		CH	Approved	25/01/2013	25/01/2013	205351
DV-2013-IVA-01148-1	DA-2013-00614-1	Immuno Pty Ltd	Mardx Diagnostics Inc (USA)	2	CT353 Bacterial infectious disease IVDs	30/01/2013		EM	Approved	4/02/2013	4/02/2013	205544
DV-2013-IVA-01255-1	DA-2013-02497-1	DiaSorin Australia Pty Ltd	Diasorin SPA (Italy)	2	CT353 Bacterial infectious disease IVDs	26/04/2013		EM	Approved	29/04/2013	29/04/2013	208811

Work Management

Task - IVD Application Without Audit - Assessment

Work Process ID:	DA-2013-00481-1	**Work Process Status:**	Completed
Work Process Manager:	IVD without audit	**Assigned To:**	IVD without audit
Default TRIM Container ID:			

Task Description

For Manufacturers Evidence check:
- appropriate Conformity Assessment Procedure/certificate for class of IVD
- scope covers the IVDs
- date issued and expiry date
- issuing body

For Device Application Form check:
- eligibility for inclusion (i.e. it is an IVD, not a medical device (non-IVD) or an excluded good)
- IVD correctly classified
- suitable GMDN code and term
- appropriate intended purpose
- answers to Device Product Characteristics questions (e.g. does application include a self-test, procedure pack etc)

If application is effective:
Record an "approved" decision and complete this task before proceeding to the notification task.

If application is not effective:
Record a "rejected" decision and enter a reason on the device application and/or this task.

Complete this task and proceed to the notification task.

Task Information

Task Information

Work Process Component:	Assessment		
Task Status:	Completed		
Planned Start:	30/01/2013	Planned End:	12/02/2013
Actual Start:	25/01/2013	Actual End:	25/01/2013
Management Comment:			
Checklist:	☒ Check Manufacturers Evidence ☒ Check Application Form Details ☒ Record Decision		
Checklist Comments:	Checklist complete and suitable for approval		
Outcome:	Approved		

Task Specifics

Delegate:	s.22(1)(a)(ii)
Decision Date:	25/01/2013

Application	Current Decision	Reason
DeviceApplication DV-2013-IVA-01001-1	Approved	N/A

Work Process Summary

Clock Information

Clock Information View Stop Clocks

Task Clock Status	Stopped		
Elapsed TGA Days:	3	Remaining TGA Days:	0

Supporting Information

Letter History :

Attached Document History :
No Task Related Documents

IVD Application

ARTG No : 205351

Class 2
Status: Approved

Application Change history

Application Progress Date	
Date received:	22/01/2013
Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? No

Does this application include a system or procedure pack? No
Is the device software or does it incorporate software?

Application Summary	
Application ID:	DV-2013-IVA-01001-1
Submission ID:	DA-2013-00481-1
Sponsor's own reference:	Novatec CT 353 class 2 bacterial
Application for:	Medical Device - IVD
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:	Immuno Pty Ltd
Sponsor ID:	12706
Agent name:	
Contact details:	s.22(1)(a)(ii)
Contact email:	s.22(1)(a)(ii)@immuno.com.au
Is this application supported by EU MDR/IVDR certification?	

Manufacturer Information	
Manufacturer's evidence:	DV-2012-MC-17681-1 :Novatec CMDCAS Goto
Manufacturer name:	Gold Standard Diagnostics Frankfurt GmbH (Germany)[44194]
Certificate issued under:	CMDCAS ISO 13485 Certification
Conformity assessment procedure:	ISO 13485 Manufacturing and Design
Assessment body:	DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen
GMDN code:	Bacterial infectious disease IVDs[CT353]
GMDN description:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases.
Intended purpose:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases.

Device Category Terms	
Device category 1:	In vitro diagnostic devices

Attached Documentation

History

25/01/2013 3:09:45 PM Approved.

Review Completed - Accepted, 25/01/2013)

Record		**Date**	
Fee:	890	Date Paid:	23/01/2013
		Date Decision:	25/01/2013

Start Dates	**Finish Dates**	**Working Days**

Application Received	22/01/2013	Payment Received	23/01/2013	1
Payment Received	23/01/2013	Application Decision	25/01/2013	3
			Total Working Days	4

CERTIFICATE

DQS Medizinprodukte GmbH

hereby certifies that the company

NovaTec Immundiagnostica GmbH
Technologie & Waldpark

Waldstraße 23 A6
63128 Dietzenbach
Germany

has implemented and maintains a **Quality Management System.**

Scope:
Design, development and manufacture of Enzyme Immuno assays for Infections disease and sexually transmitted disease In-vitro diagnostic reagents

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2003

Certificate registration No.	235931 MP23CMDR
Certificate unique ID	170533247
Effective date	2011-10-26
Expiry date	2013-12-03
Frankfurt am Main	2011-10-26

SCC Accredited CB-MS
OCSM Accrédité CCN

s.22(1)(a)(ii) s.22(1)(a)(ii)

Managing Director Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

DQS Medizinprodukte GmbH is a CMDCAS (Canadian Medical Devices Conformity Assessment System) recognized registrar.

20110204/0/EN380313

Manufacturer Evidence

Status : Approved

Certificate change history

Date received: 14/06/2013

Certificate printed: No

Variation to Evidence ID: DV-2012-MC-17681-1

Notification details

Evidence identifier: DV-2012-MC-17681-1

Submission identifier: DM-2013-04139-1

Version number: 2

Sponsor's own reference: Novatec CMDCAS

Sponsor details

Agent name:

Sponsor name: Immuno Pty Ltd

Contact details: s.22(1)(a)(ii) @immuno.com.au

Certification details

Manufacturer name: Gold Standard Diagnostics Frankfurt GmbH (Germany)[44194]

Manufacturer address as on certification: 23 Walstrasse A6 Dietzenbach Dietzenbach D63128 Germany S [141994]

Type of product:
This certification is to support an application for an in vitro diagnostic medical device (IVD)

Certificate issued under: 13

Conformity assessment procedure: ISO 13485 Manufacturing and Design

Source of certification: DQS Medizinprodukte GmbH [0297]

Certificate number: 235931mp23cmdr

Certificate issue date: 26/10/2011

Certificate expiry date: 03/12/2013

Certificate re-issue date:

Restrictions on scope:

Restriction on conformity assessment procedure:

Attached documentation:

Attached documents: CMDCAS ISO 13485 Certificate (IVDs) - 13485-2003-Canada-2013-new.p

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

s.22(1)(a)(ii) OU=TGA/O=Health

Work Management

Task - IVD Application Without Audit - Assessment

Work Process ID:	DA-2013-00614-1	Work Process Status:	Completed
Work Process Manager:	IVD without audit	Assigned To:	s.22(1)(a)(ii)
Default TRIM Container ID:			

Task Description

For Manufacturers Evidence check:
- appropriate Conformity Assessment Procedure/certificate for class of IVD
- scope covers the IVDs
- date issued and expiry date
- issuing body

For Device Application Form check:
- eligibility for inclusion (i.e. it is an IVD, not a medical device (non-IVD) or an excluded good)
- IVD correctly classified
- suitable GMDN code and term
- appropriate intended purpose
- answers to Device Product Characteristics questions (e.g. does application include a self-test, procedure pack etc)

If application is effective:
Record an "approved" decision and complete this task before proceeding to the notification task.

If application is not effective:
Record a "rejected" decision and enter a reason on the device application and/or this task.

Complete this task and proceed to the notification task.

Task Information

Task Information

Work Process Component:	Assessment		
Task Status:	Completed		
Planned Start:	05/02/2013	Planned End:	18/02/2013
Actual Start:	04/02/2013	Actual End:	04/02/2013
Management Comment:			
Checklist:	☒ Check Manufacturers Evidence ☒ Check Application Form Details ☒ Record Decision		
Checklist Comments:	Checklist complete and suitable for approval		
Outcome:	Complete		

Task Specifics

Delegate:	s.22(1)(a)(ii)
Decision Date:	04/02/2013

Application	Current Decision	Reason
DeviceApplication DV-2013-IVA-01148-1	Approved	N/A

Work Process Summary

Clock Information

Clock Information View Stop Clocks

Task Clock Status	Stopped		
Elapsed TGA Days:	4	Remaining TGA Days:	0

Supporting Information

Letter History :

Attached Document History :
No Task Related Documents

IVD Application

ARTG No : 205544

Class 2
Status: Approved

Application Change history

Application Progress Date	
Date received:	29/01/2013
Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? No

Does this application include a system or procedure pack? No
Is the device software or does it incorporate software?

Application Summary	
Application ID:	DV-2013-IVA-01148-1
Submission ID:	DA-2013-00614-1
Sponsor's own reference:	Trinity Mardx class 2 CT353 Bacterial infectious disease IVDs
Application for:	Medical Device - IVD
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:	Immuno Pty Ltd
Sponsor ID:	12706
Agent name:	
Contact details:	s.22(1)(a)(ii)
Contact email:	s.22(1)(a)(ii) immuno.com.au
Is this application supported by EU MDR/IVDR certification?	

Manufacturer Information	
Manufacturer's evidence:	DV-2012-MC-18008-1 :Mardx 13485 Goto
Manufacturer name:	Mardx Diagnostics Inc (United States Of America)[15168]
Certificate issued under:	CMDCAS ISO 13485 Certification
Conformity assessment procedure:	ISO 13485 Manufacturing and Design
Assessment body:	UL LLC
GMDN code:	Bacterial infectious disease IVDs[CT353]
GMDN description:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases.
Intended purpose:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases.

Device Category Terms	
Device category 1:	In vitro diagnostic devices

Attached Documentation

History

4/02/2013 11:03:54 AM Approved.

Review Completed - Accepted, 4/02/2013)

Record		**Date**	
Fee:	890	Date Paid:	30/01/2013
		Date Decision:	04/02/2013

Start Dates	**Finish Dates**	**Working Days**

Application Received	29/01/2013	Payment Received	30/01/2013	1
Payment Received	30/01/2013	Application Decision	04/02/2013	4
			Total Working Days	5

CERTIFICATE OF REGISTRATION

MarDx Diagnostics, Inc.

A Trinity Biotech Company
5919 Farnsworth Court
Carlsbad, CA 92008
United States

Underwriters Laboratories Inc.® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

CAN/CSA ISO 13485:2003

EN ISO 13485:2003 and ANSI/AAMI/ISO 13485:2003

The design and development, and manufacture of in vitro diagnostic test kits and reagents used in the diagnosis of disease and autoimmune status.

File Number	A14141	Effective Date	March 3, 2012
Certificate No.	11NK14883.AZBA	Expiry Date	March 2, 2015

Authorized by

s.22(1)(a)(ii)

General Manager,
UL Life and Health Sciences

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of Underwriters Laboratories Inc.

UL is a CMDCAS Recognized Registrar

Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Manufacturer Evidence

Status : Approved

Certificate change history

Date received: 22/11/2012

Certificate printed: No

New Notification

Notification details

Evidence identifier: DV-2012-MC-18008-1

Submission identifier: DM-2012-06623-1

Version number: 1

Sponsor's own reference: Mardx 13485

Sponsor details

Agent name:

Sponsor name: Immuno Pty Ltd

Contact details: s.22(1)(a)(ii) @immuno.com.au

Certification details

Manufacturer name: Mardx Diagnostics Inc (United States Of America)[15168]

Manufacturer address as on certification: 5919 Farnsworth Court CARLSBAD CALIFORNIA 92008 United States Of America

Type of product:
This certification is to support an application for an in vitro diagnostic medical device (IVD)

Certificate issued under: 13

Conformity assessment procedure: ISO 13485 Manufacturing and Design

Source of certification: UL LLC

Certificate number: 11NK14883.AZBA

Certificate issue date: 03/03/2012

Certificate expiry date: 02/03/2015

Certificate re-issue date:

Restrictions on scope:

Restriction on conformity assessment procedure:

Attached documentation:

Attached documents:
CMDCAS ISO 13485 Certificate (IVDs) - CAN-CSA ISO 13485_2003.pdf
CMDCAS ISO 13485 Certificate (IVDs) - CAN-CSA ISO 13485_2003.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

s.22(1)(a)(ii) OU=TGA/O=Health

23/11/2012

Work Management

Task - IVD Application Without Audit - Assessment

Work Process ID:	DA-2013-02497-1	Work Process Status:	Completed
Work Process Manager:	IVD without audit	Assigned To:	s.22(1)(a)(ii)
Default TRIM Container ID:			

Task Description

For Manufacturers Evidence check:
- appropriate Conformity Assessment Procedure/certificate for class of IVD
- scope covers the IVDs
- date issued and expiry date
- issuing body

For Device Application Form check:
- eligibility for inclusion (i.e. it is an IVD, not a medical device (non-IVD) or an excluded good)
- IVD correctly classified
- suitable GMDN code and term
- appropriate intended purpose
- answers to Device Product Characteristics questions (e.g. does application include a self-test, procedure pack etc)

If application is effective:
Record an "approved" decision and complete this task before proceeding to the notification task.

If application is not effective:
Record a "rejected" decision and enter a reason on the device application and/or this task.

Complete this task and proceed to the notification task.

Task Information

Task Information

Work Process Component:	Assessment		
Task Status:	Completed		
Planned Start:	02/05/2013	Planned End:	15/05/2013
Actual Start:	29/04/2013	Actual End:	29/04/2013
Management Comment:			
Checklist:	☒ Check Manufacturers Evidence ☒ Check Application Form Details ☒ Record Decision		
Checklist Comments:	Checklist complete and suitable for approval		
Outcome:	Complete		

Task Specifics

Delegate:	s.22(1)(a)(ii)
Decision Date:	29/04/2013

Application	Current Decision	Reason
DeviceApplication DV-2013-IVA-01255-1	Approved	N/A

Work Process Summary

Device Application: DiaSorin Australia Pty Ltd DV-2013-IVA-01255-1 Class: CLAS2 FLAGS:

Task: IVD Application Without Audit - Adminstration - Completed

Task: IVD Application Without Audit - Assessment - Completed

Task: IVD Application Notification - Completed

Letter: Delegate Checklist - Finalised on: 29/04/2013

Clock Information

Clock Information View Stop Clocks

Task Clock Status	Stopped		
Elapsed TGA Days:	2	Remaining TGA Days:	0

Supporting Information

Letter History:

Attached Document History :

No Task Related Documents

IVD Application

ARTG No : 208811

Class 2
Status: Approved

Application Change history

Application Progress Date	
Date received:	24/04/2013
Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? No

Does this application include a system or procedure pack? No
Is the device software or does it incorporate software?

Application Summary	
Application ID:	DV-2013-IVA-01255-1
Submission ID:	DA-2013-02497-1
Sponsor's own reference:	Bacterial infectious disease IVDs
Application for:	Medical Device - IVD
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:	DiaSorin Australia Pty Ltd
Sponsor ID:	54278
Agent name:	
Contact details:	s.22(1)(a)(ii)
Contact email:	s.22(1)(a)(ii)@diasorin.com.au
Is this application supported by EU MDR/IVDR certification?	

Manufacturer Information	
Manufacturer's evidence:	DV-2011-MC-07060-3 :DiaSorin Italy G-MED ISO 13485 CMDCAS Goto
Manufacturer name:	DiaSorin Italia SpA (Italy)[8004]
Certificate issued under:	CMDCAS ISO 13485 Certification
Conformity assessment procedure:	ISO 13485 Manufacturing and Design
Assessment body:	Laboratoire National de metrologie et dEssais (LNE)
GMDN code:	Bacterial infectious disease IVDs[CT353]
GMDN description:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases.
Intended purpose:	IVDs that are intended to be used in testing to provide information about infection with or exposure to one or a number of bacterial diseases

Device Category Terms	
Device category 1:	In vitro diagnostic devices

Attached Documentation

History

29/04/2013 3:07:16 PM Approved.

Review Completed - Accepted, 29/04/2013)

Record		**Date**	
Fee:	890	Date Paid:	26/04/2013
		Date Decision:	29/04/2013

Start Dates	**Finish Dates**	**Working Days**

Application Received	24/04/2013	Payment Received	26/04/2013	2
Payment Received	26/04/2013	Application Decision	29/04/2013	3
			Total Working Days	5

LNE
Le progrès, une passion à partager

Certification Médical-Santé G MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 19839 rev. 5

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

DIASORIN S.p.A.
Via Crescentino, snc
13040 SALUGGIA (VC) ITALY

pour les activités
for the activities

Conception, développement, fabrication, distribution, ventes et services après-vente pour les dispositifs médicaux de diagnostic in vitro et analyseurs pour le diagnostic et la gestion de maladies infectieuses, cancer, désordres endocriniens et auto-immunes pour les instituts de soins médicaux et de recherche.

Design, development, manufacturing, distribution, sales and after-sales servicing of in-vitro medical devices and analyzers for the diagnosis and management of infectious diseases, cancer, endocrine and autoimmune disorders for the medical care and research related industries.

réalisées sur le(s) site(s) de
performed on the location(s) of

DIASORIN S.p.A.
Via Crescentino, snc, 13040 SALUGGIA (VC) ITA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2003

Début de validité / *Effective date* **November 29th, 2016 (included)**
Valable jusqu'au / *Expiry date* :**December 31st, 2018 (included)**
Etabli le / *Issued on* : **November 24th, 2016**

s.22(1)(a)(ii)

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

SCC Accredited CB-MS OCSM Accrédité CCN

LNE N° 19839–5
LNE: CMDCAS recognized registrar / This certificate is issued according to the rules of G-MED certification and CMDCAS program requirements
Renouvelle le certificat 19839-4

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié par l'autorité compétente française en matière de dispositifs médicaux n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

Manufacturer Evidence

Status : Approved

Certificate change history

Date received: 05/12/2016

Certificate printed: No

Variation to Evidence ID: DV-2011-MC-07060-3

Notification details

Evidence identifier: DV-2011-MC-07060-3

Submission identifier: DM-2016-06925-1

Version number: 4

Sponsor's own reference: DiaSorin Italy G-MED ISO 13485 CMDCAS

Sponsor details

Agent name:

Sponsor name: DiaSorin Australia Pty Ltd

Contact details: s.22(1)(a)(ii)

Certification details

Manufacturer name: DiaSorin Italia SpA (Italy)[8004]

Manufacturer address as on certification: Via Crescentino Saluggia Vercelli 13040 Italy S [185773]

Type of product:
This certification is to support an application for an in vitro diagnostic medical device (IVD)

Certificate issued under: 13

Conformity assessment procedure: ISO 13485 Manufacturing and Design

Source of certification: Laboratoire National de metrologie et dEssais (LNE)

Certificate number: 19839 rev.5

Certificate issue date: 29/10/2010

Certificate expiry date: 31/12/2018

Certificate re-issue date: 29/11/2016

Restrictions on scope:

Restriction on conformity assessment procedure:

Attached documentation:

Attached documents: ISO 13485 Certificate (IVDs) - ISO 13485 CMDCAS Cert n°19839 rev.5.pd

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

s.22(1)(a)(ii) OU=TGA/O=Health