



This form, when completed, will be classified as 'For official use only'.
 For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

5. Device details (non-IVD devices only)

Copy this section for each kind of medical device

Device name			
GMDN code e.g. 34179			
GMDN term (e.g. stent, vascular, coronary artery)			
Unique Product Identifier (For Class III and class AIMD only) For further information, refer to the Australian Regulatory Guidelines for Medical Devices http://www.tga.gov.au/industry/devices-argmd.htm .			
List of variants e.g. diameter and length ranges (For Class III and class AIMD only) For further information, refer to the Australian Regulatory Guidelines for Medical Devices http://www.tga.gov.au/industry/devices-argmd.htm .			
Select the device's Australian classification level Refer to <i>Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2</i> .	Class I <input type="checkbox"/> Class IIa <input type="checkbox"/> Class IIb <input type="checkbox"/> Class III <input type="checkbox"/> AIMD <input type="checkbox"/>	Applicable classification rule (Australia) e.g. 3.4(4)(a)	

Select the device's EU classification level

(For MRA CE certification applications)
Refer to *COUNCIL DIRECTIVE 93/42/EEC, ANNEX IX, III. CLASSIFICATION.*

Class I	<input type="checkbox"/>	Applicable classification rule (EU) e.g. rule 5 (For MRA CE certification applications)
Class IIa	<input type="checkbox"/>	
Class IIb	<input type="checkbox"/>	
Class III	<input type="checkbox"/>	
AIMD	<input type="checkbox"/>	
Is the device supplied sterile?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the device single-use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the device incorporate a measuring function?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the device an Active medical device?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the device incorporate software?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

5.1. For devices incorporating ancillary medicinal substances, material of animal, microbial, or recombinant origin

<p>What is the manufacturer's intended purpose for the device?</p> <p>For example: Used to display and/or record real-time arterial blood pressure, intracranial (inside the skull) pressure, cerebral perfusion (blood flow in the brain) pressure, temperature, respiratory (breathing) rate, electrical activity of the heart, pulsatile (pulsing) heart rate, and/or oxygen saturation (percentage of oxygen in the blood).</p> <p>The device is used by a clinician for the monitoring of a patient and for the diagnosis of illness or disease.</p>	
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<p>Description of the device</p> <p>For example: The device is a diagnostic device intended to measure physiological parameters during walking. The device detects and records body signals via attached sensors.</p> <p>The following components are part of the device:</p> <p>Software</p> <p>Microcontroller</p> <p>Battery</p> <p>Hardware interface</p> <p>The device detects and records information on a portable hard drive. With the help of the associated PC software, the recorded information can be read and analysed by the clinician. Clinical parameters are detected via vibrations measured by the device. The devices are supplied non-sterile.</p>	
<p>Device incorporates a medicinal substance that has an action that is ancillary to the device</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Device incorporates an extract from human blood or plasma that has an action that is ancillary to the device</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Device incorporates material or substances of animal origin or was manufactured using materials of animal origin</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Device incorporates or was manufactured using material or substances of microbial origin</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Device incorporates material or substances produced using recombinant technology</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>