



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>.

6. IVD medical device details

Copy this section for each kind of IVD

Device name			
GMDN code e.g. 34179			
GMDN term (e.g. stent, vascular, coronary artery)			
Unique Product Identifier (For Class 4 IVDs) For further information, refer to IVD guidance documents http://www.tga.gov.au/industry/ivd-guidance.htm .			
List of variants (For Class 4 IVDs- Immunohaematology reagents only) For further information, refer to IVD guidance documents http://www.tga.gov.au/industry/ivd-guidance.htm .			
Classification Refer to <i>Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2A</i> or to guidance documents http://www.tga.gov.au/industry/ivd-classification.htm .	Class 1 <input type="checkbox"/> Class 2 <input type="checkbox"/> Class 3 <input type="checkbox"/> Class 4 <input type="checkbox"/>	Applicable classification rule (Australia)	

What is the manufacturer's intended purpose for the device?	
Description of the device	