Manufacturer Evidence

Status : Versioned

Certificate change history

s22 [redacted]

Version 3: Accepted. No changes noted s22 [redacted], 1/04/2010)

s22 [redacted]

Version 8. Accepted. EC Certificate renewal. Change of Scope has been declared and ARTG entries are still covered. (s22 [redacted] 26/05/2015)

Version 9 - Accepted. Updated EC Certificate added (increase in scope) The sponsor has indicated in the manufacturers evidence application that 'the scope of the certificate has changed' and the 'scope of the certificate still covers all the ARTG entries linked to this evidence'. (s22 [redacted], 8/08/2016)

Date received:	05/08/2016
Certificate printed:	No

Variation to Evidence ID: DV-20061110-MC-027677-11

Notification details

Evidence identifier:	DV-20061110-MC-027677-11
Submission identifier:	DM-2016-04545-1
Version number:	9
Sponsor's own reference:	Optimed Annex II

Sponsor details

Agent name:	47G [redacted]
Sponsor name:	Pyramed Pty Ltd
Contact details:	s22 [redacted]

Certification details

Manufacturer name:	Optimed Medizinische Instrumente (Germany)[28983]
Manufacturer address as on certification:	Ferdinand-Porsche-Strasse 11 Ettlingen 76275 Germany S [126074]

Type of product:
This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	02
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	Dekra Certification GmbH [0124]

Certificate number:	50066-16-07
Certificate issue date:	18/09/2006
Certificate expiry date:	04/08/2019
Certificate re-issue date:	05/08/2016
Restrictions on scope:	

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.

Attached documentation:

Attached documents: EC Certificate - CE-Certificate - 50066-16-07 Rev 0.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

CN=s22 [redacted] /OU=TGA/O=Health