



Manufacturer Evidence

Status : Versioned

Certificate change history

s22

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

s22

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

Date received: 20/05/2015

Certificate printed: No

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

Notification details

Evidence identifier: DV-20061110-MC-027677-11

Submission identifier: DM-2015-03609-1

Version number: 8

Sponsor's own reference: Optimed Annex II

Sponsor details

Agent name: 47G

Sponsor name: Pyramed Pty Ltd

Contact details: s22

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: 50066-16-06

Certificate issue date: 18/09/2006

Certificate expiry date: 04/08/2016

Certificate re-issue date: 16/04/2015

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.

Attached documentation:

Attached documents:  Updated EC Certificate - CE-Certificate - 50066-16-06 Rev 7.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

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History

CN=s22/OU=TGA/O=Health