



## Manufacturer Evidence

Status : Versioned

### Certificate change history

s22

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

Date received: 28/01/2014

Certificate printed: No

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

### Notification details

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

Submission identifier: DM-2014-00548-1

Version number: 6

Sponsor's own reference: Optimed Annex II 50066-16-05

### 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: 05/08/2011

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 5.pdf

**Supporting documents:**

#	Document Type	Description	Method

**Related Active ARTG Entry Information:**

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## History

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