



Manufacturer Evidence

Status : Versioned

Certificate change history

s22

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

s22

Date received: 04/03/2015
Certificate printed: No
Variation to Evidence ID: DV-20061110-MC-027677-11

Notification details

Evidence identifier: DV-20061110-MC-027677-11
Submission identifier: DM-2015-01476-1
Version number: 7
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: 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 6.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

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History

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