Manufacturer Evidence

Status : Approved

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)
Version 10: Updated EC Certificate attached with increase in scope. The sponsor has confirmed that the scope of the certificate has changed and that all linked ARTG entries are still covered. s22 [redacted] 9/08/2019)

Date received:	05/08/2019
Certificate printed:	No

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

Notification details

Evidence identifier:	DV-20061110-MC-027677-11
Submission identifier:	DM-2019-05432-1
Version number:	10
Sponsor's own reference:	Optimed - Annex II - 50066-16-08

Sponsor details

Agent name:	
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:	50066-16-08
Certificate issue date:	05/08/2019
Certificate expiry date:	26/05/2024
Certificate re-issue date:	
Restrictions on scope:	

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.

Attached documentation:

Attached documents: Updated EC Certificate - Optimed - Annex II - 50066-16-08 - exp 26-05-24

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

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

FINAL ANALYSIS REPORT

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen

The available data indicates neither a product defect, nor a change in the characteristics or performance of the products used. It is also assumed that the use of products in accordance with the intended use would lead to no complications. The information obtained in this case indicate that the specifications of the information for users (IFU) have not been implemented:

- According to the specifications for the intended use (see IFU) the sinus-XL stent has an indication solely for straight sections of the vena cava.
  In the present case the stent was used for the treatment of a stenosis in the junction between the brachiocephalic vein and superior vena cava.
- According to the specifications for the intended use (see IFU) to prevent stent migration in the venous area a stent size should be used that is 5-7% higher than the actual vessel diameter.
  In the present case a stent size (20mm) was used, which was 20% below the measured vessel diameter (24mm).
- The stent is not recognized in accordance with user information for the treatment of vessel perforation.
- The stent is not intended for repositioning. However, since the stent migrated into the atrium, in this particular circumstance the physician tried to reposition the stent.
  optimed assumes that this attempt was considered an emergency situation and was well within the margin of discretion of the treating physician. However, in this situation optimed cannot guarantee the safety and functionality of the sinus-XL stent, because it is outside of its intended use.

It cannot be ruled out that the vessel wall was already perforated during the placement of the first stent. However, a perforation by a stent with a diameter smaller than that of the vessel is unlikely. Furthermore, a perforation by the delivery system is conceivable, however, highly unlikely during its intended use. Up until now, optimed has no knowledge of such complaints. Due to the disclosed aspects optimed assumes this to be an application error.

optimed GmbH

Ettlingen, 28 September 2016

s22 [redacted]

Safety Officer for Medical Devices