

# EC Certificate

For the Quality Assurance System  
according the directive 93/42/EEC, Annex II  
excluding section (4)



As a notified body of the European Union, DEKRA Certification GmbH certifies,  
that the company

**OptiMed Medizinische Instrumente GmbH**  
Ferdinand-Porsche-Straße 11 • 76275 Ettlingen, Germany

applies a quality assurance system for the medical devices listed in the annex  
according to the directive 93/42/EEC annex II. The approval is based on the result  
of the re-certification audit report no. 50066-Z4-00, the decision dated 05.08.2011  
and is only valid in connection with the successful performance of the annual  
surveillance audits.

Date of the first certification:	<u>21.05.1997</u>	Date of the last recertification:	<u>05.08.2011</u>
This certificate is valid until:	<u>04.08.2016</u>	Certificates registration No.:	<u>50066-16-06</u> English version

Stuttgart, 05.08.2011  
DEKRA Certification GmbH  
Handwerkstraße 15, 70565 Stuttgart, Germany  
Notified Body ID-number: 0124



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-992.94.16

# Annex to the EC Certificate 50066-16-06 dated 05.08.2011

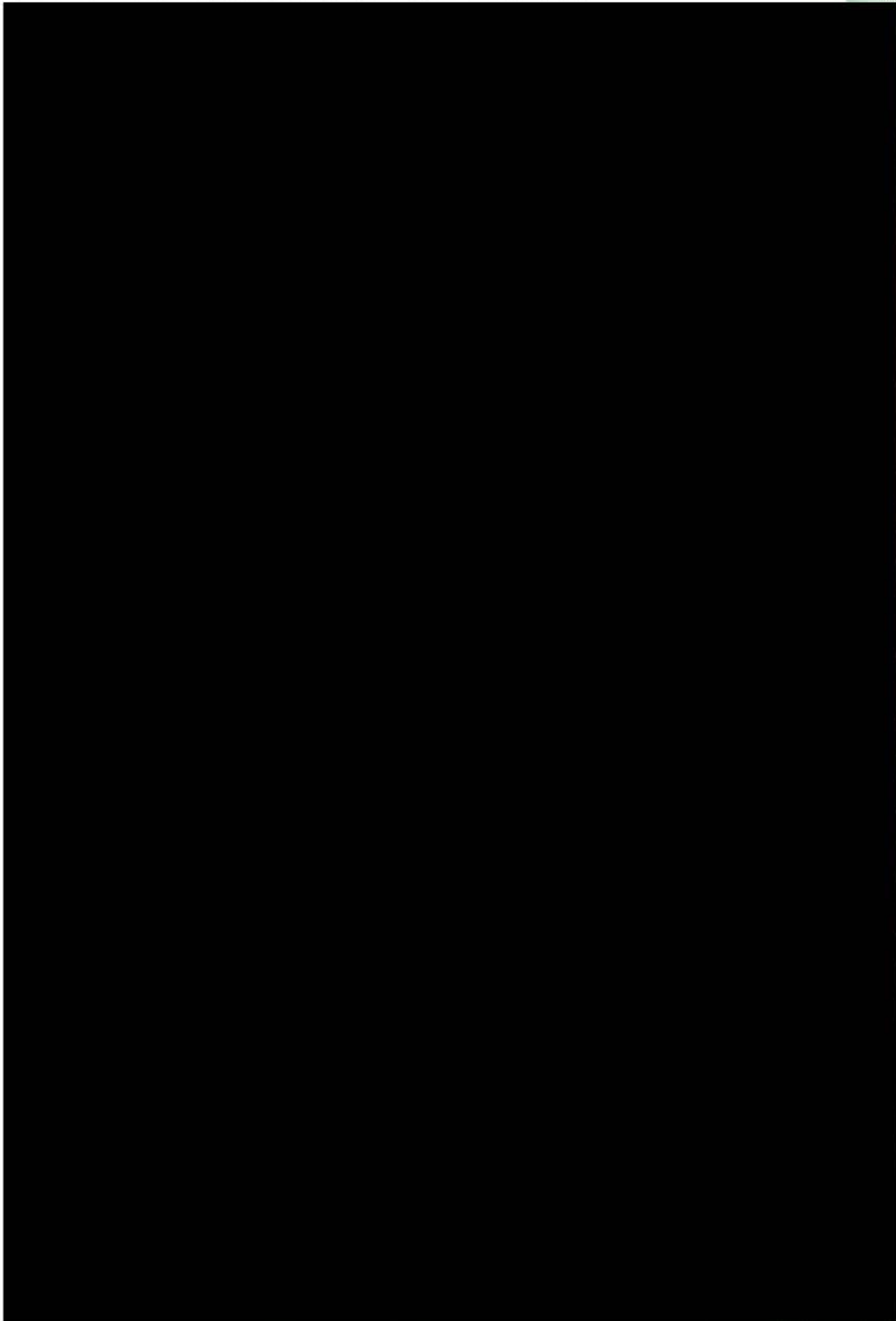
English version

Revision status: 5

Date: 17.01.2014

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Devices/device categories included in the certificate



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# Annex to the EC Certificate 50066-16-06 dated 05.08.2011

English version

Revision status: 5

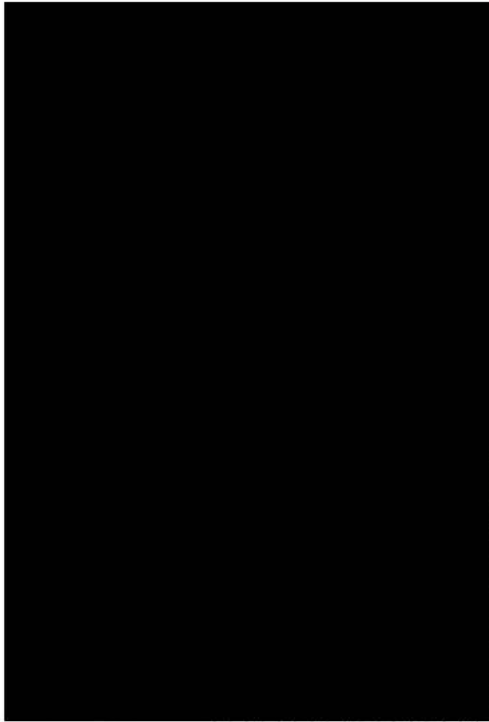
Date: 17.01.2014

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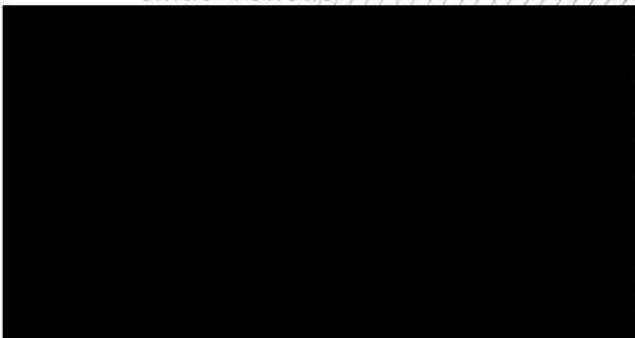


Class II b:

**Implants: Nitinol Stents**



sinus-Venous





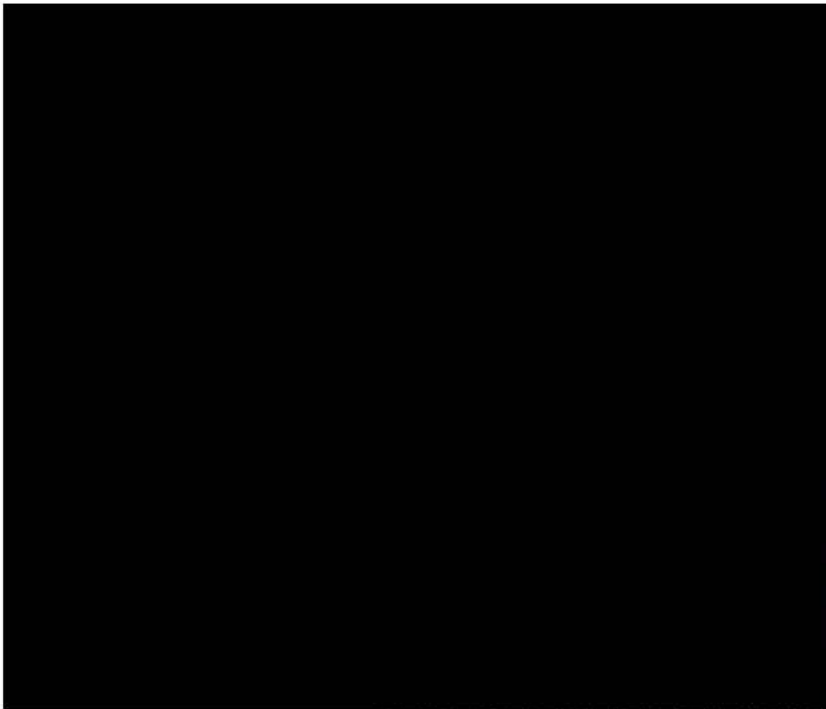
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For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.