EC Certificate

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

DEKRA Certification

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

Opti*Med* 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:	21.05.1997	Date of the last recertification:	05.08.2011
This certificate is valid until:	04.08.2016	Certificates registration No.:	50066-16-06 English version

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

[redacted]

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

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

English version

Revision status: 6 Date: 28.11.2014

Devices/device categories included in the certificate

[redacted]

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

English version

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Class II b:

Implants: Nitinol Stents

[redacted]

sinus-Venous

[redacted]

[redacted]

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

English version

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.