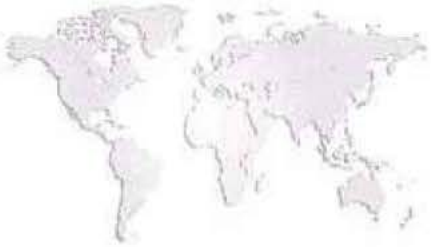
EC CERTIFICATE

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-Z5-00, the decision dated 2016-07-28 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-08-05 to 2019-08-04

Certificate registration No.: 50066-16-07

s22

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

GmbH Stuttgart; 2016-07-28
mber: 0124

Annex to the EC Certificate 50066-16-07 dated 2016-07-28

Devices/device categories included in the certificate

s22 [redacted]

Class II b:

- Implants: Nitinol Stents

s22 [redacted]

- sinus-Venous

s22 [redacted]

Annex to the EC Certificate 50066-16-07 dated 2016-07-28

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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.