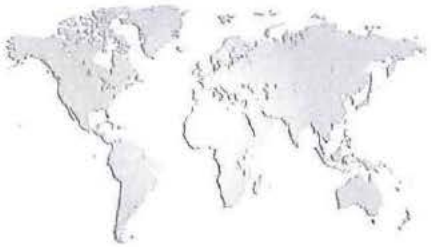
EC CERTIFICATE

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

Certified location:

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50066-Z6-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-08-05 to 2024-05-26

Registration No.: 50066-16-08

s22 [redacted]

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

DEKRA Certification GmbH Stuttgart; 2019-06-26
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 0 dated 2019-08-05

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 No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 0 dated 2019-08-05

Devices/device categories included in the certificate:

s22

[redacted]

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.

s22

[redacted]

DEKRA Certification GmbH, Stuttgart, 2019-06-26
Notified Body ID-number: 0124