EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex V

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Bosch + Sohn GmbH & Co. KG

Certified location:

Bahnhofstraße 64, 72417 Jungingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50539-Z6-00, the decision dated 2017-04-28 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-04-29 to 2020-04-28

Registration No.: 50539-17-04

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

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-04-28
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50539-17-04

Revision status: 0

Valid from 2017-04-29 to 2020-04-28

Devices/device categories included in the certificate:

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- Non active medical devices with measuring function
  - non invasive aneroid sphygmomanometers

Class II a:

- Devices for monitoring vital physiological parameters
  - Noninvasive blood pressure units and systems
  - Thermometer, electronic
  - Thermometer, infrared
  - 24-hour ambulatory blood pressure monitor

- Evaluation software for blood pressure units and systems

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