

CERTIFICATE

for the

Quality Assurance System



As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for manufacture and final inspection by the company

Bosch + Sohn GmbH u. Co. KG
Bahnhofstraße 64 • 72417 Jungingen, Germany

Approval is based on the decision dated 23.04.2009 and the result of the report no. 50539-Z4-00 and is performed in accordance with the stipulations of

Annex V, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex V, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 13.01.1995

This certificate is valid until: 28.04.2014

Date of the last recertification: 29.04.2009

Certificate-registration No.: 50539-17-02
English version

DEKRA Certification GmbH
Stuttgart, 23.04.2009



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

Annex to the Certificate 50539-17-02 dated 23.04.2009

English version

Revision status: 0

Date: 29.04.2009

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Devices/device categories included in the certificate

Class II a:

- Non invasive blood pressure units, electronic, manual;
boso privat automatic
- Non invasive blood pressure units, electronic, automatic;
bosotron 2
- Non invasive blood pressure system for determination of ABI;
boso-ABI system 100

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the manufacturing steps associated with product conformity and metrological requirements.

- Non invasive aneroid sphygmomanometers



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