

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
Heinz Kurz GmbH

Tübinger Straße 3, 72144 Dusslingen, Germany

Certified location/s:

Tübinger Straße 3, 72144 Dusslingen, Germany
Im Steinig 75/1, 72144 Dusslingen, 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. 50158-Z6-00, the decision dated 2018-08-02 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-09-04 to 2023-09-03

Registration No.: 50158-16-06

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-08-02
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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

Annex to the EC Certificate No. 50158-16-06

Valid from 2018-09-04 to 2023-09-03

Revision status of the annex: 0 dated 2018-08-02

Devices/device categories included in the certificate:

Class II b:

- Middle Ear Implants for Tympanoplasty
- Middle Ear Implants for Stapedioplasty
- Implant for Ventilation and Draining of the Middle Ear
- Eyelid Implants
- Vocal Fold Medializing Implants
- Implants for Rhinoplasty



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