

# 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



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://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



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2018-08-02  
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