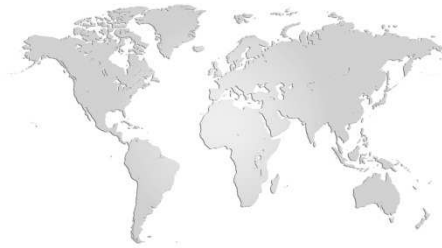


# EC CERTIFICATE

## 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  
**BUSCH & CO. GmbH & Co. KG**

Unterkaltenbach 17-27, 51766 Engelskirchen, Germany

**Certified location/s:**

Unterkaltenbach 17-27, 51766 Engelskirchen, 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. 50234-Z6-00, the decision dated 2019-05-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-05-25 to 2024-05-24

Registration No.: 50234-16-07



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2019-05-20  
Notified Body ID-number: 0124



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. 50234-16-07

Valid from 2019-05-25 to 2024-05-24

Revision status of the annex: 1 dated 2020-06-26

Devices/device categories included in the certificate:

## Class II a:

Rotary instruments for medical use

- Rotary steel, carbide, ceramic and diamonds instruments, rotary ceramic abrasives, polishers and brushes for dental purposes
  - Bur, dental, steel / MD 0106 / UMDNS-Code 16-669
  - Bur, dental, carbide / MD 0106 / UMDNS-Code 16-668
  - Bur, dental, diamond / MD 0106 / UMDNS-Code 16-670
  - Polisher, burnisher / MD 0106 / UMDNS-Code 16-412
  - Abrasives, dental / MD 0106 / UMDNS-Code 13-350
  - Brush, Prophylaxis- / MD 0106 / UMDNS-Code 16-369
  - Mandrel / MD 0106 / UMDNS-Code 12-429
- Rotary steel, carbide, ceramic and diamonds instruments, ceramic abrasives for podiatry
  - Bur, podiatry / MD 0106 / UMDNS-Code 10-522



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-06-26  
Notified Body ID-number: 0124

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