

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

MEGADENTA Dentalprodukte GmbH

Scope of certification:

Design and development, manufacture and distribution of dental-medical and dental-technical products

Certified location:

Carl-Eschebach-Straße 1 A, 01454 Radeberg, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50007-Z7-00.

Certificate registration no.:	50007-14-01	Certificate valid from:	2021-04-29
Validity of previous certificate:	2021-04-28	Certificate valid to:	2024-04-28



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-03-23



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
MEGADENTA Dentalprodukte GmbH

Carl-Eschebach-Straße 1 A, 01454 Radeberg, Germany

Certified location:

Carl-Eschebach-Straße 1 A, 01454 Radeberg, 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. 50007-Z6Ü1-00, the decision dated 2019-07-24 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-07-24 to 2023-04-28

Registration No.: 50007-16-09




Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-07-24
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. 50007-16-09

Valid from 2019-07-24 to 2023-04-28

Revision status of the annex: 1 dated 2020-04-07

Devices/device categories included in the certificate:

Class II a:

- Dental filling material
 - C-Fill MH
 - Hybrisun
 - Megafill MF
 - Megafill MH
 - Megafill MH ceram
 - Megafill Flow
 - Megafill Flow ceram
 - Megafill Bio
 - P-Fill
 - N-Fill
 - N-Fill Flow
 - C-Fill Flow
 - T-Fill
 - T-Fill Eco Pulver
 - T-Fill Eco Flüssigkeit
 - CAMOUFLAGE
 - C-Cid
 - C-Bond
 - C-Bond ceram
 - N-Bond
 - Fiber-Bond
 - C-Cement
 - C-Cement Flow
 - C-Prime S plus
 - C-Prime SE
 - C-Seal
 - N-Seal
 - Megafix (aqua set)
 - Megacem (aqua set)
 - Megafix (powder/liquid)
 - Megacem Basic (powder/liquid)

Annex to the EC Certificate No. 50007-16-09

Valid from 2019-07-24 to 2023-04-28

Revision status of the annex: 1 dated 2020-04-07

Devices/device categories included in the certificate:

Class II a:

- Denture base material
 - MEGA-A Pulver
 - MEGA-A Flüssigkeit
 - MEGA-L Pulver
 - MEGA-L Flüssigkeit
 - MEGA-F Pulver
 - MEGA-F Flüssigkeit
 - Denture Line Pulver
 - Denture Line Flüssigkeit
 - Denture Line Soft Flüssigkeit
 - Megaseal Universal
 - Megaseal N
 - Fasern



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-07
Notified Body ID-number: 0124

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