



EU Technical Documentation Assessment Certificate



This is to certify that the company

GDF Gesellschaft für dentale Forschung und Innovationen GmbH

Dieselstr. 5-6
61191 Rosbach
Germany

SRN: DE-MF-000009196

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

**Conformity Assessment based on a Quality Management System and on Assessment of
Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIa and IIb listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	230469 MDR2017B
Certificate ID	1000123322
Effective date	2023-06-28
Expiry date	2028-01-11
Frankfurt am Main,	2023-06-28



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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(active medical devices)

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(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.



Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000009196
Certificate ID: 1000123322

Device categories and variants covered by this certificate:

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Dental-Verblendung
Models: Resin facing material
Risk classification: IIa
Basic-UDI-DI: +D933 32 00001W
Intended purpose: Resin facing materials are composites used for covering different framework materials for the design of dental restorations.

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Verbundwiederherstellungsmaterial, dental
Models: Zahnfüllungsmaterial auf Kompositbasis
Risk classification: IIa
Basic-UDI-DI: +D933 11 00001T
Intended purpose: Dental filling materials on composite basis are used to build up or to preserve tooth structures.

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Wiederherstellungsmaterial, dental, Krone und Brücke
Models: Temporary crown and bridge materials
Risk classification: IIa
Basic-UDI-DI: +D933 30 00001U
Intended purpose: Temporary crown and bridge materials are used for the fabrication of individual temporary crowns and bridges.

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Verbundwiederherstellungsmaterial, dental, sonstige
Models: Fixing composite/root pin cement
Risk classification: IIa
Basic-UDI-DI: +D933 17 00001Z
Intended purpose: Fixing composites/root pin cements are used for the adhesive, permanent bonding of restorative materials to restorative materials, to hard tooth structure or to a denture base, or to secure root pins in the root canal.

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Zahnprothese, Klebemittel
Models: Dentin- /Schmelz-Adhäsive
Risk classification: IIa
Basic-UDI-DI: +D933 23 00001W
Intended purpose: The product group "Dentin and enamel adhesives" comprises bonding agents for the application in adhesive restorative dentistry.



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Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Zubehörkit, Wiederherstellungsmaterial, dental
Models: Dental colors for individualization
Risk classification: IIa
Basic-UDI-DI: +D933 33 00001X
Intended purpose: Dental colors for individualization are composite-based colors that are used to individualize or characterize a wide variety of dental materials.

Device category: **MDN 1103 Non-active dental implants and dental materials**
Product name: Wiederherstellungsmaterial, dental
Models: Fräsbare CAD/CAM-Materialien
Risk classification: IIa
Basic-UDI-DI: +D933 31 00001V
Intended purpose: The millable CAD/CAM materials are intended for the fabrication of dental prosthetic restorations using dental milling systems. The millable CAD/CAM materials are intended for use by the dental technician in a dental laboratory. Depending on the type of material, the product can be used to create temporary or permanent dental restorations.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnprothese, Klebemittel
Models: Attachment glue
Risk classification: IIa
Basic-UDI-DI: +D933 16 00001Y
Intended purpose: Attachment glues are used for the adhesive, permanent bonding of telescopic or conical crowns or prefabricated retaining elements to the framework material.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnprothesenbasis- Harz
Models: Light-curing denture lacquer
Risk classification: IIa
Basic-UDI-DI: +D933 28 00001.
Intended purpose: The light-curing denture lacquer is used to chemically smooth the surface of a denture base after finishing.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnprothesenbasis-Harz, selbstaushärtend bzw. Zahnprothesenbasis-Harz, wärmeaushärtend bzw. Zahnprothesenunter-fütterung, hart
Models: Denture base materials
Risk classification: IIa
Basic-UDI-DI: +D933 29 00001
Intended purpose: Denture base materials are intended for the fabrication of splints, partial dentures, full dentures and model dentures.



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Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnbleichmittel
Models: Dental bleaching gel
Risk classification: IIa
Basic-UDI-DI: +D933 13 00001V
Intended purpose: A dental bleaching gel is a product used to brighten teeth that are devitalized or discoloured by diseases, injuries, medicines or iatrogenically.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Dental-Ätzflüssigkeit
Models: Dental etching gel
Risk classification: IIa
Basic-UDI-DI: +D933 20 00001T
Intended purpose: Dental etching gel is used to etch enamel and/or dentin.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Dental-Schienenmaterial
Models: Glass fibres with light curing resin matrix
Risk classification: IIa
Basic-UDI-DI: +D933 10 00001S
Intended purpose: The areas of application for glass fiber include the manufacture of glass fiber-reinforced bridges and implant dentures, periodontal splints to stabilize loose teeth, the use as space maintainers to protect gaps between teeth, and the use as orthodontic retainers to stabilize the position of teeth after an orthodontic treatment.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zement, orthodontisch
Models: Fixing composite for orthodontic attachments
Risk classification: IIa
Basic-UDI-DI: +D933 19 00001.
Intended purpose: Fixing composites for orthodontic attachments are materials for the adhesive bonding of orthodontic retainer elements.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnprothese, Klebmittel
Models: Bonding agent
Risk classification: IIa
Basic-UDI-DI: +D933 21 00001U
Intended purpose: Bonding agents are used to bond various restorative materials to the framework material.



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Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Zahnprothese, Klebemittel
Models: Orthodontic bonding agent
Risk classification: IIa
Basic-UDI-DI: +D933 24 00001X
Intended purpose: Orthodontic bonding agents are materials for conditioning hard tooth structures and other restorative surfaces in an orthodontic treatment.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Gummischutz, dental
Models: Light-curing denture lacquer
Risk classification: IIa
Basic-UDI-DI: +D933 15 00001X
Intended purpose: The light-curing denture lacquer is used to chemically smooth the surface of a denture base after finishing.

Device category: **MDN 1209 Non-active non-implantable dental materials**
Product name: Dental-Verblendung
Models: Framework covering material
Risk classification: IIa
Basic-UDI-DI: +D933 27 00001-
Intended purpose: Framework covering materials are composite-based materials for covering different framework materials in preparation for subsequent veneering with veneering composite or denture resin.

Examinations and tests performed:

230469 A209421MED_02_Fräsbare CAD/CAM-Materialien dated 11.10.2022
230469 A209421MED MDR2017B Tender Fiber dated 17.05.2023

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-12	170781917	Optimizing the purpose of the products
02	2023-04-13	1000117650	Addition of the product Tender Fiber and further products with MDN 1209