



CERTIFICATE



This is to certify that the company

breident GmbH & Co. KG

Weissenhorner Straße 2
89250 Senden
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design, development, production, servicing and distribution of dental products, dental implantologic Abutments and dental materials including alloys, dental; elastomers, silicone rubber; screws; dental porcelains; dental veneer; adhesives, denture; dental, hand instrument, other; restorative materials, dental, crown and bridge; denture base resins; denture base resins, heat-cured; composite restorative material kits, dental, heat-cured; dental precision attachment; teeth, dental prosthesis; denture reliners, soft; prostheses, dental, fixed; dentures, partial; prostheses, maxillofacial.

- **AUS (a), CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	287638 MDSAP16
Certificate unique ID	170781341
Effective date	2022-08-26
Expiry date	2025-08-25
Frankfurt am Main	2022-08-26



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director
August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Marc Goedecke
Product Manager



DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.
The validity of this certificate can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 287638 MDSAP16
Certificate unique ID: 170781341
Effective date: 2022-08-26

bredent GmbH & Co. KG

Weissenhorner Straße 2
89250 Senden
Germany

Audited site

492923

bredent GmbH & Co. KG
Weissenhorner Straße 2
89250 Senden
Germany

REPs FEI No.: site scope and country-specific requirements

Design, development, production, servicing and distribution of dental products, dental implantologic Abutments and dental materials including alloys, dental; elastomers, silicone rubber; screws; dental porcelains; dental veneer; adhesives, denture; dental, hand instrument, other; restorative materials, dental, crown and bridge; denture base resins; denture base resins, heat-cured; composite restorative material kits, dental, heat-cured; dental precision attachment; teeth, dental prosthesis; denture reliners, soft; prostheses, dental, fixed; dentures, partial; prostheses, maxillofacial.

- AUS (a), CND, JPN, USA (a,b,c,d)

REPs FEI No.: F002479

492924

bredent GmbH & Co. KG
Siemensstraße 3
89250 Senden
Germany

Design, development, production, servicing and distribution of dental products, dental implantologic Abutments and dental materials including alloys, dental; elastomers, silicone rubber; screws; dental porcelains; dental veneer; adhesives, denture; dental, hand instrument, other; restorative materials, dental, crown and bridge; denture base resins; denture base resins, heat-cured; composite restorative material kits, dental, heat-cured; dental precision attachment; teeth, dental prosthesis; denture reliners, soft; prostheses, dental, fixed; dentures, partial; prostheses, maxillofacial.

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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821