



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 certificate and applicable country-specific requirements:

Design, development, production, servicing and distribution of dental products and dental materials including alloys, dental; elastomers, silicone rubber; screws; dental porcelains; matrix bands, dental; 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; Dentaclean impression and denture disinfectant.

- 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 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope
(full references are listed in the annex)

Certificate registration no. 287638 MDSAP16
Certificate unique ID 170750841
Effective date 2019-09-19
Expiry date 2021-07-05
Frankfurt am Main 2019-09-19



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate
Certificate registration No.: 287638 MDSAP16
Certificate unique ID: 170750841
Effective date: 2019-09-19



bredent GmbH & Co. KG

Weissenhorner Straße 2
89250 Senden
Germany

Audited site

DUNS No., site scope and country-specific requirements

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

Design, development, production, servicing and distribution of dental products and dental materials including alloys, dental; elastomers, silicone rubber; screws; dental porcelains; matrix bands, dental; 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; Dentaclean impression and denture disinfectant.
- CND, JPN, USA (a,b,c,d)
DUNS No.: 341086190

bredent GmbH & Co. KG
Siemensstraße 3
89250 Senden
Germany

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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. 16/2013 RDC ANVISA n. 23/2012 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