



CERTIFICATE



This is to certify that the company

breident medical 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, manufacturing, servicing and distribution of dental and dental implantologic products including laser therapeutic; laser delivery systems, waveguide, burs, dental steel; burs, dental zircon; prostheses, dental, implantable; dental precision attachment; denture reliners, soft; prosthesis implantation instruments, dental
-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.	349344 MDSAP16
Certificate unique ID	170777659
Effective date	2021-09-30
Expiry date	2024-07-08
Frankfurt am Main	2021-09-30



DQS Medizinprodukte GmbH

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



Annex to certificate
Certificate registration No.: 349344 MDSAP16
Certificate unique ID: 170777659
Effective date: 2021-09-30



breident medical GmbH & Co.KG

Weissenhorner Straße 2
89250 Senden
Germany

Audited site

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

545711
breident medical GmbH & Co.KG
Siemensstraße 3
89250 Senden
Germany

Design, development, manufacturing, servicing and distribution of dental and dental implantologic products including laser therapeutic; laser delivery systems, waveguide, burs, dental steel; burs, dental zircon; prostheses, dental, implantable; dental precision attachment; denture reliners, soft; prosthesis implantation instruments, dental

-AUS (a), CND, JPN, USA (a, b, c, d)
REPs FEI No.: F002479

545710
breident medical GmbH & Co.KG
Weissenhorner Straße 2
89250 Senden
Germany

Design, development, manufacturing, servicing and distribution of dental and dental implantologic products including laser therapeutic; laser delivery systems, waveguide, burs, dental steel; burs, dental zircon; prostheses, dental, implantable; dental precision attachment; denture reliners, soft; prosthesis implantation instruments, dental

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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