



CERTIFICATE



This is to certify that the company

W & H Dentalwerk Bürmoos GmbH

Ignaz-Glaser-Straße 53
5111 Bürmoos
Austria

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 and development, distribution and production of active dental equipment, active surgical equipment, units and accessories for the area of dentistry surgery and orthopaedics as follows: powered dental instruments and equipment, powered surgical instruments and equipment, disposable surgical instruments, injection handpieces.

- **AUS (a), BRA, 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. | 004911 MDSAP16 |
| Certificate unique ID | 170718345 |
| Effective date | 2018-08-03 |
| Expiry date | 2021-08-02 |
| Frankfurt am Main | 2018-07-30 |



DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is authorised 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.: 004911 MDSAP16
Certificate unique ID: 170718345
Effective date: 2018-08-03



W & H Dentalwerk Bürmoos GmbH

Ignaz-Glaser-Straße 53
5111 Bürmoos
Austria

Audited site

DUNS No., site scope and country-specific requirements

W & H Dentalwerk Bürmoos GmbH

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5111 Bürmoos
Austria

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

DUNS No. 300238441

W & H Dentalwerk Bürmoos GmbH

Werner-Bader-Strasse 1
5111 Bürmoos
Austria

Design and development, distribution and production of active dental equipment, active surgical equipment, units and accessories for the area of dentistry surgery and orthopaedics as follows: powered dental instruments and equipment, powered surgical instruments and equipment, disposable surgical instruments, injection handpieces.

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

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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 |