



# CERTIFICATE



This is to certify that the company

## METOXIT AG

Emdwiesenstrasse 6  
8240 Thayngen  
Switzerland

with the organizational units/sites as listed in the annex

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

Scope of certification:

Design, development and production of ceramic blanks and corresponding dyeing liquids for the production of dental-prosthetic restorations.

**-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)

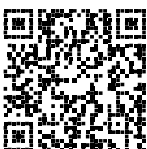
|                              |                |
|------------------------------|----------------|
| Certificate registration no. | 066501 MDSAP16 |
| Certificate unique ID        | 1000118304     |
| Effective date               | 2023-11-02     |
| Expiry date                  | 2026-11-01     |
| Frankfurt am Main            | 2023-11-02     |



### 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.

The validity of this certificate can only be verified by the QR-code.



**Annex to certificate**  
**Certificate registration No.: 066501 MDSAP16**  
**Certificate unique ID: 1000118304**  
**Effective date: 2023-11-02**

## **METOXIT AG**

Emdwiesenstrasse 6  
8240 Thayngen  
Switzerland

### **Audited site**

**METOXIT AG**  
Emdwiesenstrasse 6  
8240 Thayngen  
Switzerland

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

Design, development and production of ceramic blanks and corresponding dyeing liquids for the production of dental-prosthetic restorations.  
**-AUS (a), CND, JPN, USA (a,b,c,d)**  
**REPs FEI No.: F000637**

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

| <b>Abbreviation</b> | <b>Jurisdiction</b> | <b>Reference</b>   |
|---------------------|---------------------|--|
| AUS                 | Australia           | (a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure<br>(b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure |
| BRA                 | Brazil              | RDC ANVISA n. 665/2022<br>RDC ANVISA n. 551/2021<br>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<br>Japan PMD Act (as applicable)   |
| USA                 | United States       | (a) 21 CFR Part 803<br>(b) 21 CFR Part 806<br>(c) 21 CFR Part 807<br>(d) 21 CFR Part 820<br>(e) 21 CFR Part 821  |