



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7053GB451251117

Final assessment report no.
7053AU16F

Effective date
2025-11-17

Expiry date
2028-06-27

This is to certify that

edelweiss dentistry products gmbh

Dammstraße 68, 6922 Wolfurt, Austria

has introduced, applies and maintains a management system at the site(s) listed on the following page(s).

This management system has been audited and found to conform to the quality management systems standard

ISO 13485:2016 and the following country-specific requirements

Australia – Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 (without 1.6)

Canada – Medical Devices Regulations SOR/98-282, Part 1 (applicable requirements)

Japan – MHLW Ministerial Ordinance No. 169, Articles 4 to 68; PMD Act (as applicable)

United States of America – 21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D); 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2025-11-17

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



Markus Bianchi
Certification Body Operations

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact medcert-info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820114 EN Rev 6 2025.07.16

MDSAP RECOGNISED AUDITING ORGANIZATION: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



Certificate no.: 7053GB451251117
Place and date: Hamburg, 2025-11-17

Activities and products/services covered by this certificate

Design and development, manufacturing and distribution of

- Dental materials
 - Polymer based Materials for fixed prostheses (inlays, onlays, crowns, pediatric crowns, bridges, veneers)
 - Endodontic filling materials
 - Plastic materials for direct insertion (polymers and auxiliaries)
 - Luting materials (polymers)
 - Dentine and enamel adhesives

Sites covered by this certificate and associated (partial) scopes

edelweiss dentistry products gmbh, Dammstraße 68, 6922 Wolfurt, Austria
Facility ID: F007899

Design and development, manufacturing and distribution of

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 - Polymer based Materials for fixed prostheses (inlays, onlays, crowns, pediatric crowns, bridges, veneers)
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