

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
7046GB445231214

Final assessment report no.  
7046AU14F

Effective date  
2023-12-14

Expiry date  
2025-12-08

This is to certify that

**Harvard Dental International GmbH**

Margaretenstraße 2-4, 15366 Hoppegarten, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

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

**EN ISO 13485:2016**

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

Place and date  
Hamburg, 2023-12-14

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



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

  
Lorenz Runge  
Director Certification Body

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

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ACCREDITED UNIT: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (currently registered as DNV MEDCERT GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

### Sites covered by this certificate

Harvard Dental International GmbH, Margaretenstraße 2-4, 15366 Hoppegarten, Germany

Harvard Dental International GmbH, Robert-Bosch-Straße 2, 25335 Elmshorn, Germany

### Activities and products/services covered by this certificate

Design and development, manufacturing, final inspection and distribution of

- Dental materials
  - Impression trays
  - Impression materials
  - Luting materials (cements, polymers)
  - Bite registration materials
  - Bleaching agents for internal and external dental bleaching, professional dental use only
  - Dentin- and enamel adhesives
  - Endodontic filling materials
  - Pit and fissure sealants
  - Filling cements
  - Conditioning agents
  - Plastic materials for direct insertion (polymers)
  - Prophylaxis materials
  - Temporary filling materials
  - Temporary crown and bridge materials
  - Pulp capping materials
  - Retraction materials
  - Protective films
  - Core build-up materials
  - Cavity lining materials
  - Relining materials
  - Waxes
  - Materials for fixed prosthesis (polymers)
  - Materials for removable dentures (polymers)
  - Materials for surface preparation (etch, prime)
  - Accessories for the use of dental materials
- Otoplastic materials
- Podoplastic materials