

# EC Certificate of Conformity

## The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**Harvard Dental International GmbH**  
**Margaretenstraße 2 – 4**  
**15366 Hoppegarten**  
**Germany**

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

**Effective date:** 2020-06-09  
**Expiry date:** 2023-12-09

Report No.: 7046PS11F  
Process No.: QS – 7046  
Certificate No.: 7046GB410200609

Hamburg, 2020-06-09

  
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MEDCERT Certification Body  
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-237.10.15

## Appendix of EC Certificate of Conformity

Process No.: QS – 7046

Certificate No.: 7046GB410200609

### List of locations included in the scope of certificate

**Robert-Bosch-Straße 2  
25335 Elmshorn  
Germany**

– End of list –

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**Appendix of EC Certificate of Conformity**

Process No.: QS – 7046

Certificate No.: 7046GB410200609

**List of products / product categories included in the scope of certificate****Dental materials**

- **Luting materials (cements, polymers)**
- **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)**
- **Temporary filling materials**
- **Temporary crown and bridge materials**
- **Pulp capping materials**
- **Protective films (longterm)**
- **Core build-up materials**
- **Cavity lining materials**
- **Relining materials**
- **Materials for fixed prostheses (polymers)**
- **Materials for removable dentures (polymers)**
- **Materials for surface preparation (etch, prime)**

– End of list –

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