

# EC Declaration of Conformity

We, the

**Harvard Dental International GmbH**  
**Margaretenstrasse 2-4**  
**15366 Hoppegarten**  
SRN: DE-MF-000010845

hereby declare under our sole responsibility that the medical device with the intended purpose:

belonging to the  
UMDNS-group 10-036, adhesives, liquid,  
GMDN-code 62474, Dental prosthesis priming agent,  
EMDN-group Q010299, devices for prosthetic dentistry - others,

namely

**VITA ADIVA C-Prime,**  
REF: FACP5  
**basic UDI-DI: ++EHARVIT4205C**

is in compliance with the requirements of the Directive 93/42/EEC and in accordance with Article 120 of the Regulation (EU) 2017/745

## **Conformity Assessment**

*Procedure:*

*According to Annex II excluding section 4 of the Directive 93/42/EEC.*

*Classification:*

*According to Annex IX Rule 8 of the Directive 93/42/EEC: Class IIa.*

*Reference Standards:*

*EN ISO 13485:2016 + AC:2018 + A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes*

*EN ISO 14971:2019 + A11:2021 - Medical devices - Application of risk management to medical devices*

*EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

*EN ISO 20417:2021 - Information to be supplied by the manufacturer*

*ISO 10993 applicable parts - Biological evaluation of medical devices*

*EN ISO 7405:2018 - Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*

*EN 1641:2009 - Dentistry - Medical devices for dentistry - Materials*

*Notified Body:*

*Medcert Zertifizierungs- und Prüfungsgesellschaft für Medizin GmbH*

*Pilatuspool 2*


*20355 Hamburg*

*Identification-Number: 0482*

*Certificate No.: 7046GB410200609*

Hoppegarten, 2023-11-24

Place, date

  
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Dr. Marian Casny  
Authorised Person for Regulatory Compliance