

# **EC Declaration of Conformity**

We, the

**P.L. Superior Dental Materials GmbH  
Stiller Weg 15a  
22607 Hamburg  
SRN. DE-MF-000005251**

hereby declare under our sole responsibility that the medical device  
with the intended purpose: luting of crowns, inlays and bridges, cavity lining and temporary  
filling,

belonging to the  
UMDNS-group 16-710, cement, dental, zinc phosphate,  
GMDN-code 16710, Zinc phosphate dental cement,  
EMDN-code Q010101, dental restorative devices,  
namely

**CEM-X UNIVERSAL,  
REF: MF.012005,  
basic UDI-DI: ++EPLSNAS551CF**

is in compliance with the requirements of the Regulation (EU) 2017/745 of the European  
Parlament and of the Council.

## **Conformity Assessment**

*Procedure:*

*According to Annex IX of the Regulation (EU) 2017/745.*

*Classification:*

*According to Annex VIII, Chapter III, Rule 8 & 19 of the Regulation (EU) 2017/745: 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*

*EN ISO 9917-1:2007 - Water-based cements - Part 1: Powder/liquid acid-base cements*

*This declaration is effective for products placed on the market as of the date of issue. Any modifications of the device not authorized by above declarant will invalidate this declaration.*

*Notified Body:*

*DNV Medcert GmbH*

*Pilatuspool 2*

*20355 Hamburg*


*Identification-Number: 0482*

*Certificate No.: 1649GB448231211*

**Validity: 08 December 2027**

**Hamburg, 2025-05-12**

Place, date

  
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Dr. Marian Casny  
Authorised Person for Regulatory Compliance  
PRRC