# 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, bridges, inlays and onlays with glassionomer,

belonging to the
UMDNS-group 16-704, cement, dental, glass ionomer,
GMDN-code 16704, Glass ionomer dental cement,
EMDN-code Q010101, dental restorative devices,

namely

## Glass Cem,

**REF: MF.000551,**
**basic UDI-DI: ++EPLSNAS513C7**

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; Chapter I Section 2 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 reqirements*
*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, 2024-06-04
Place, date

Dr. Marian Cashy
Authorised Person for Regulatory Compliance
PRRC