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: composite based dental luting,

belonging to the
UMDNS-group 16-731, composite restorative materials, dental, other,
GMDN-code 35870, Dental composite resin,
EMDN-code Q010101, dental restorative devices,

namely

LUTE-X SE,

REF: MF.012002,
basic UDI-DI: ++EPLSNAS464CK

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 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

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

Dr. Marian Casny
Authorised Person for Regulatory Compliance
PRRC