

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: dental pulp capping and temporary filling of root canals,

belonging to the
UMDNS-group 17-619, restorative materials, dental, other,
GMDN-code 47232, Calcium hydroxide suspension,
EMDN-code Q010199, devices for conservative dentistry and endodontics - others,

namely

RootCal XR,
REF: MF.012001,
basic UDI-DI: ++EPLSNAS540CA

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

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