

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: creating of temporary crown or bridges,

belonging to the

UMDNS-group 16-723, restorative materials, dental, crown & bridge,

GMDN-code 31783, Temporary dental crown/bridge,

EMDN-code Q010205, resins and dental crowns,

namely

ProviCrown,

REF: MF.000954, MF.000955, MF.002543, MF.002586,

basic UDI-DI: ++EPLSNAS316C3

is in compliance with the requirements of the Regulation (EU) 2017/745 of the European
Parliament 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 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

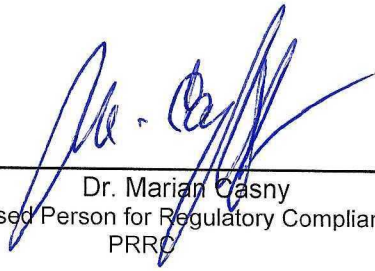
Identification-Number: 0482

Certificate No.: 1649GB448231211

Validity: 08 December 2027

Hamburg, 2024-06-04

Place, date



Dr. Marian Casny
Authorised Person for Regulatory Compliance
PRRO