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: core build-up with light cured composite

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

namely

BuildFix Pro,

REF: **MF.001590**
basic UDI-DI: ++EPLSNAS127BW

is in compliance with the requirements of the Directive 93/42/EEC and in accordance with Article 120 of the Regulation (EU) 2017/745, including the amendments made by Regulation (EU) 2023/607, Article 1.

Conformity Assessment

Procedure:
According to Annex II excluding section 4 of the Directive 93/42/EEC.

Classification:
According to Annex IX Rule 8 of the Directive 93/42/EEC: 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 4049:2019 - Polymer-based restorative materials

Notified Body:
Medcert Zertifizierungs- und Prüfungsgesellschaft für Medizin GmbH
Pilatuspool 2
20355 Hamburg
Identification-Number: 0482
Certificate No.: 1649GB410190708
Validity: ***31 December 2028***

Hamburg,2024-06-04
Place, date

Dr. Marian Casny
Authorised Person for Regulatory Compliance
PRRC