

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 Max (Automix),

REF: MF.002389

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 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

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