EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
1649GB448231211	1649AU26F	2023-12-11	2027-12-08

This is to certify that the quality system of

P.L. Superior Dental Materials GmbH

Stiller Weg 15A, 22607 Hamburg, Germany

SRN: DE-MF-000005251

For design, production, final product inspection/testing and distribution of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2023-12-11

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Certificate no.: 1649GB448231211
Place and date: Hamburg, 2023-12-11

Preceding certificate

Certificate no.	Issue date	Identification of changes
n/a	n/a	n/a

Sites covered by this certificate

P.L. Superior Dental Materials GmbH, Stiller Weg 15A, 22607 Hamburg, Germany

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Certificate no.: 1649GB448231211
Place and date: Hamburg, 2023-12-11

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1103	Q0101	Devices for conservative dentistry and endodontics
MDN 1103	Q0102	Devices for prosthetic dentistry
MDN 1209	Q0101	Devices for conservative dentistry and endodontics
MDN 1209	Q0102	Devices for prosthetic dentistry
MDN 1209	Q0105	Instruments for dentistry, single-use
MDN 1214	Q0304	Otology devices
MDN 1214	Z121390	Various orthopaedic and traumatology instruments

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