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

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

P. L. Superior
Dental Materials GmbH
Private Label Dental Materials in Superior Quality

MEDCERT 0482

EU Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	P.L. Superior Dental Materials GmbH
Manufacturer address and contact details	Stiller Weg 15A 22607 Hamburg
Single Registration Number (SRN) (if available)	DE-MF-000005251

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	DNV MEDCERT GmbH □ See attached schedule
Notified body number (if applicable)	0482 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	1649GB410190708 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	09.12.2023 □ See attached schedule
End date of extended validity/transition period	31.12.2028 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

P. L. Superior
Dental Materials GmbH
Private Label Dental Materials in Superior Quality MEDCERT 0482

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Medical Device(s)**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

The above Manufacturer's Declaration is valid for all medical devices manufactured by our company.

Signed for and on behalf of the manufacturer:

P. L. Superior Dental Materials GmbH

24.11.2023

Dr. Marian Casny, PRRC

mcasny@sc-polymer.com

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
1649GB445231211	1649AU26F	2023-12-11	2025-12-08

This is to certify that

P.L. Superior Dental Materials GmbH

Stiller Weg 15A, 22607 Hamburg, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-12-11

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

For the issuing office
DNV MEDCERT GmbH
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.: 1649GB445231211
Place and date: Hamburg, 2023-12-11

Sites covered by this certificate

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

Activities and products/services covered by this certificate

Design and development, manufacturing, final inspection and distribution of

- Dental materials
  - Impression trays
  - Impression materials
  - Luting materials (cements, polymers)
  - Bite registration materials
  - Bleaching agents for internal and external dental bleaching, professional dental use only
  - Dentin- and enamel adhesives
  - Endodontic filling materials
  - Pit and fissure sealants
  - Filling cements
  - Conditioning agents
  - Plastic materials for direct insertion (polymers)
  - Prophylaxis materials
  - Temporary filling materials
  - Temporary crown and bridge materials
  - Pulp capping materials
  - Retraction materials
  - Protective films
  - Core build-up materials
  - Cavity lining materials
  - Relining materials
  - Waxes
  - Materials for fixed prosthesis (polymers)
  - Materials for removable dentures (polymers)
  - Materials for surface preparation (etch, prime)
  - Accessories for the use of dental materials
- Otoplastic materials
- Pedoplastic materials