

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to Regulation (EU) 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	Merz Dental GmbH
Manufacturer address and contact details	Kieferweg 1, 24321 Lütjenburg
Single Registration Number (SRN) (if available)	DE-MF-000008303

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)	See attachment
Notified body number (if applicable)	See attachment
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attachment
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attachment
End date of extended validity/transition period	See attachment

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.

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We, as the manufacturer declare under our sole responsibility:

- for the attached **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** 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 Certificates** as attached

- Directive Certificates covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

Expired after 20 March 2023:

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

- A notified body has issued the attached certificate for the MDR-compliant QMS. The devices continue to comply with the MDD.

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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.

Signed for and on behalf of the manufacturer:

Company: Merz Dental GmbH

Name: Moritz Wicklein, Person Responsible for Regulatory Compliance

Contact Details: moritz.wicklein@merz-dental.de



Wicklein,
Moritz
2025.06.03
12:02:06
+02'00'

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)² (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Artificial Teeth	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
M-PM Disc	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
artBloc Temp	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
M-PM crystal	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
ArtConcept PLUS	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
PEEK BioSolution	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2027-12-31	Not applicable
PEEK Nature	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
BDLoad	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
Weropress	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
Promolux	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
PremEcoLine	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable

² for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Combipress	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
PEL Prothetik Color System	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
M-PRINT Splint	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	DNV MEDCERT GmbH CE0482	2028-12-31	Not applicable
M-ZR Discs	0439GB410191205	2024-05-27	MEDCERT GmbH, CE0482	Not applicable	2028-12-31	Not applicable

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

MERZ DENTAL GmbH
Kieferweg 1
24321 Lütjenburg
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2019-12-05

Expiry date: 2024-05-27

Report No.: QS-0439FS28F

Process No.: QS – 0439

Certificate No.: 0439GB410191205

Hamburg, 2019-12-05


MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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Zentralstelle der Länder
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Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 0439

Certificate No.: 0439GB410191205

List of locations included in the scope of certificate

MERZ DENTAL GmbH
Eetzweg 20
24321 Lütjenburg
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 0439

Certificate No.: 0439GB410191205

List of products / product categories included in the scope of certificate

- **Dental materials**
 - **Abutments**
 - **Accessories for ceramic materials for fixed prostheses (colouring liquids)**
 - **Artificial teeth**
 - **Cavity lining materials**
 - **Ceramic, polymer- and metal materials for fixed prostheses (crowns, bridges, inlays, onlays, veneers)**
 - **Core build-up materials**
 - **Dentine and enamel adhesives**
 - **Endodontic filling materials**
 - **Luting materials (cements, polymers)**
 - **Materials for removable prostheses (polymers)**
 - **Materials for surface preparation (etch, prime)**
 - **Materials for the fabrication of occlusal splints and drilling templates (polymers)**
 - **Materials for the protection of the pulp and for periodontal use**
 - **Pit and fissure sealants**
 - **Plastic materials for direct insertion (polymers, cements, metals)**
 - **Preformed complete removable dentures (polymers)**
 - **Relining materials**
 - **Temporary crown and bridge-, inlay- and onlay materials**
 - **Temporary luting materials (cements)**

- **Disinfectants**

– End of list –

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