Certificate of Compliance

(according to Notified Body Confirmation Letter Article 120 MDR)

Merz Dental EUDAMED-SRN:	DE-MF-000008303
Product Group:	Artificial Teeth
Product Names:	**integral anteriors + posteriors,** **artegral life anteriors + posteriors, artegral life HD posteriors,** **Polystar Selection EDITION anteriors +posteriors,** **Polystar Selection EDITION HD posteriors,** **Polystar Selection EDITION 2 posteriors,** **DeltaForm posteriors, DeltaForm HD posteriors**
Product Group:	Denture Base Resin
Product Names:	**Weropress Polymer + Monomer, Weropress LT Monomer,** **Combipress N Polymer, Combipress LM Polymer,** **Combipress N / LM Monomer** **Promolux Polymer + Monomer,** **Promolux High Impact Polymer + Monomer**

We,
Merz Dental GmbH, Kieferweg 1, D - 24321 Luetjenburg (Germany)

declare in sole responsibility that the medical devices comply with the relevant acceptance criteria and fulfil the specifications of the last declaration of conformity issued under and covered by the Directive 93/42/EEC (MDD).
Even though our certificate issued by our notified body has been withdrawn due to withdrawal of Directive 93/42/EEC (MDD), our notified body confirms in its confirmation letter Certification No 0439GB454241212 that Merz Dental signed a written agreement under MDR that allows us an exemption from the applicable assessment procedure. This exemption and its transition timelines are covered by Article 120.3c of Regulation 2017/745/EU (MDR) (as amended by EU 2023/607).

The applicable transition timeline for these Risk Class IIa devices is: **31 December 2028**.

Confirmation letter issuing notified body:

Notified Body:	**DNV MEDCERT GmbH**
NANDO No:	0482
Adress:	Pilatuspool 2, D-20355 Hamburg, Germany
Certification No:	**0439GB454241212**

Wicklein, Moritz
2025.02.10
16:20:30 +01'00'

Moritz Wicklein
(Person Responsible for Regulatory Compliance acc. to MDR Art. 15 – moritz.wicklein@merz-dental.de)