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 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	**Saremco Dental AG**
Manufacturer address and contact details	Gewerbestrasse 4, 9445 Rebstein, Switzerland Phone +41 71 775 80 90 Fax +41 71 775 80 99 info@saremco.ch www.saremco.ch
Single Registration Number (SRN)	**CH-MF-000042507**

Authorised Representative name	**Clinicus Dental UG (haftungsbeschränkt)**
Authorised Representative address and contact details	Gartenstr. 29, 49744 Geeste, Germany Phone +49 5907 / 94 98 60 Fax +49 5907 / 94 98 65 info@clinicus-dental.de
Single Registration Number (SRN)	**DE-AR-000015062**

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

We, as the manufacturer declare under our sole responsibility 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** as listed in the attached schedule

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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

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 will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**

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

- **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.

On behalf of the manufacturer:

Saremco Dental AG

Rebstein, 01 July 2024

Sven Hauser / Managing Director

sven.hauser@saremco.ch

SAREMCO

Schedule of Devices

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

Device name or Basic UDI-DI (under MDR application)	**MDD Certificate References of the devices under MDR application, and the NB Identification**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged / contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
++D9311000Y9	Certification as follows: G1 055 249 0010 REV. 01; NB 0123 Q5 055249 0012 Rev. 02; NB 0123	2024-05-26	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	2028-12-31	n/a
++D9312000YG	Certification as follows: G1 055 249 0010 REV. 01; NB 0123 Q5 055249 0012 Rev. 02; NB 0123	2024-05-26	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	2028-12-31	n/a
++D9313000YP	Certification as follows: G1 055 249 0010 REV. 01; NB 0123 Q5 055249 0012 Rev. 02; NB 0123	2024-05-26	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	2028-12-31	n/a
++D9314000YW	Certification as follows: G1 055 249 0010 REV. 01; NB 0123 Q5 055249 0012 Rev. 02; NB 0123	2024-05-26	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	**TÜV SÜD Product Service GmbH**, Ridlerstr. 65, 80339 Munich, Germany **CE 0123**	2028-12-31	n/a