DECLARATION OF CONFORMITY UE

Manufacturer:	**DEAS S.r.l.** Via dell'Industria 49 Castel Bolognese (RA), 48014, Italia
SRN CODE:	IT-MF-000013017
Device family:	Suction oral care devices
Intended use:	Disposable devices for the oral hygiene of adult and child patients in assisted ventilation, as an aid to reduce the risk of VAP (ventilator associated pneumonia) occurrence, connectable to suction devices.
Basic UDI-DI	080334260 ORAL-CARE R8
Identification codes:	List at page 2

The undersigned DEAS S.r.l., manufacturer of the medical devices "Suction oral care devices", whose codes are listed below, declares under our sole responsibility:

a) that the devices listed below comply with the applicable requirements of EU Regulation 2017/745;

b) that the devices listed below are classified as **Class IIa** devices;

c) that the devices are sold in **NON STERILE** packaging;

d) that the medical devices are certified by the notified body TÜV SUD Product Service GmbH – Ridlerstrasse 65 – 80339 Munch, CE 0123, according to the procedure described by the enclosure V of Directive 93/42/EEC and s.m.i., in accordance with the transitional provisions of Article 120.2 of Regulation (EU) 2017/745.

Expire date: 20/03/2023

Attachments:

Copy of the Certificate n° G2 17 12 31998 026

	The manufacturer DEAS S.r.l. Francesca Biondi Regulatory Office On behalf of The Legal Representative Domenico Scardovi

Castel Bolognese, 26/05/2022

CODES LIST		
REF	DESCRIPTION	GMDN
ST01 NS	Suction tooth brush for Oral Care	48037