EU Declaration of Conformity according to Medical Device Directive 93/42/EEC

Manufacturer name:	Cedic S.r.l
Manufacturer registered place of business:	Via Liberazione, 63/9 IT – 20068 Peschiera Borromeo (MI)
SRN:	IT-MF-000019323
Products:	Please refer to the below list
Risk Class:	Is, Rule I Annex IX
Conformity assessment procedure:	MDD, Annex V and VII
Common Specifications:	N/A
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
NB Identification Number:	0123
Certificate N°:	G2S 047541 0022 Rev.00
Certificate Validity:	Certificate Expiry date: 26/05/2024 End date of extended validity: 31/12/2028
DoC Validity:	31/12/2028

REFERENCE: Council Directive 93/42/EEC concerning Medical Devices (MDD) amended by Directive 2007/47/EC, Medical Device Regulation (EU) 2017/745 (MDR) amended by Regulation (EU) 2023/607

In relation to Council Directive 93/42/EEC and Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 we, as the manufacturer declare under our sole responsibility, that:

- the medical device(s) covered by the present declaration of conformity meet the provisions of the Council Directive 93/42/EEC
- for the above mentioned Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the medical device(s) covered by the present declaration of conformity and we as their manufacturer are in compliance with the conditions listed in Article 120.3c for continued placing on the market and putting into service

Place & date of issue: Peschiera Borromeo, 24/05/2024

Position	Name	Signature	Date
Global Head of Technical, Research & Development - PRRC	Khalid Azzouzi		24/05/2024

Products List

Product Code	Product Ref.	Product Name
F00065	F00065	ENPlus Screw Cap Adapter
F00198	A120	40 mm Screw Cap to ENPlus Adapter
F00200	A125	ENConnect Hydration bottle adapter
F00202	A130	ENConnect ENPlus to 40mm ScrewCap Adapter