Cedic
Divisione Biomedicale
Via Liberazione, 63/9 20068 Peschiera Borromeo (MILAN) ITALY Phone 02-55300174 - Fax 02-55301487

DECLARATION OF CONFORMITY

REFERENCE: Council Directive 93/42/EEC concerning Medical Devices (MDD) amended by Directive 2007/47/EC.

We herewith declare that the marketed CE marked Medical Devices, as specified in the below product list, belonging to the family of:

STERILE ADAPTERS FOR ENTERAL APPLICATIONS	CODE	CLASSIFICATION MDD, Annex IX (Rule)
Compat spike adapter	F 00063 (12195946)	Is (1 sterile)
EN Plus screw cap adapter	F 00065	Is (1 sterile)
Screw cap adapter with thin spike	F 00068	Is (1 sterile)
40mm Screw Cap to ENPlus Adapter	F 00198 (A120)	Is (1 sterile)
ENConnect ENPlus to 40mm ScrewCap Adapter	F 00202 (A130)	Is (1 sterile)
Hydration Bottle Adapter	F 00200 (A125)	Is (1 sterile)

are in compliance with conformity assessment procedure according to MDD, Annex V (Certificate N° G2S 047541 0022 Rev.00, by TÜV SÜD Product Service GmbH., Ridlerstr. 65 – 80339 Munich Germany, Notified Body, N° 0123) and Annex VII.
The first CE Certificate was issued with N° G2S 02 10 47541 001 on 04th October 2002.

The Devices fulfill the Essential Requirements of the M.D.D., Annex I and Cedic S.r.l. will maintain an adequate vigilance system.

The Declaration of Conformity is issued in compliance with the applicable regulations defined in the Device Master File regarding the Sterile adapter for enteral application family.

Cedic Srl is exclusively responsible for the declaration of conformity.

EC certification expiry date: 26 May 2024

Declaration of Conformity expiry date: 26 May 2024

Peschiera Borromeo Date: 08 October 2019

Giovanni Calzi
Chief Operating Officer

CEDIC S.r.l.
DOCUMENTO
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