



**Dichiarazione di Conformità
Declaration of Conformity**

B. Braun Avitum
{ B. Braun Avitum Italy S.p.A. }
Form-ID SOP-MBC621
Version: 0
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La sottoscritta

We

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO)
Italy

Dichiara sotto la propria responsabilità
che il/i prodotto/i

Enteroport Plus Sets

(Codici Articolo vedi Allegato I)

è/sono in conformità alle seguenti direttive:

Direttiva del Consiglio 93/42/CEE del 14 Giugno 1993
riguardante i dispositivi medici

Procedura di conformità:

In accordo all'Allegato II regola 3
della Direttiva 93/42/CEE

Classificazione

In accordo all'Allegato IX della Direttiva 93/42/CEE:
Classe IIa, Regola 2

Certificato CE Nr.

G1 019717 0032 Rev. 00

Ente Notificato:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Monaco
Germania
Nr. di identificazione 0123

Data prima marcatura CE:

1997-01

Doc #: 27/14-RA-cb

Doc Rev #: 7.0

Rev date: 2020-01-15

Validità della dichiarazione:

dal 2020-01-16

fino al 2024-05-26

hereby declare in our own responsibility
that the product/s

Enteroport Plus Sets

(article numbers see attachment I)

is/are in compliance with the following directives:

Council Directive 93/42/EEC of 14 June 1993
on medical devices

Conformity assessment procedure:

according to annex II clause 3
of Council Directive 93/42/EEC

Classification

according to annex IX of Council Directive 93/42/EEC:
Class IIa, rule 2

EC Certificate No.

G1 019717 0032 Rev. 00

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
Identification number 0123

Date of first CE-marking:

1997-01

Doc #: 27/14-RA-cb

Doc Rev #: 7.0

Rev date: 2020-01-15

Validity of this declaration:

from 2020-01-16

until 2024-05-26

Mirandola, 16/01/2020


Francesco Benatti
Managing Director

Mirandola, 2020-01-16


Dr. Giuliana Gavioli
QM / RA Director

Allegato I / Attachment I

Nr. Art. /	Descrizione Articolo /	Classe – Regola /
Art. No.	Article Description	Class – Rule
8721688	Enteroport® plus FL	II a – Rule 2
8721726	Enteroport® plus Set 500	II a – Rule 2
8721734	Enteroport® plus Set 1000	II a – Rule 2
8721735	Enteroport® plus Set 1000 Safety	II a – Rule 2
8721736	Enteroport® plus ENFit™ Set 1000 ml – Transition	II a – Rule 2
8721737	Enteroport® plus ENFit™ Set 1000 ml	II a – Rule 2
8721742	Enteroport® plus Set 2500	II a – Rule 2
8721744	Enteroport® plus Set Universal Adapter	II a – Rule 2
8721745	Enteroport® plus Set Universal Adapter Safety	II a – Rule 2
8721746	Enteroport® plus ENFit™ Set with Universal Adapter – Transition	II a – Rule 2
8721747	Enteroport® plus ENFit™ Set with Universal Adapter	II a – Rule 2
8721748	Enteroport® plus ENFit™ Set with ENPlus spike – Transition	II a – Rule 2
8721749	Enteroport® plus ENFit™ Set with ENPlus spike	II a – Rule 2
8721750	Enteroport® plus Set Multispike	II a – Rule 2

Mirandola, 16/01/2020


Francesco Benatti
Managing Director

Mirandola, 2020-01-16


Dr. Giuliana Gavioli
QM / RA Director