



**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**

<b>Nr. Art. /</b>	<b>Descrizione Articolo /</b>	<b>Classe – Regola /</b>
<b>Art. No.</b>	<b>Article Description</b>	<b>Class – Rule</b>
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