

La sottoscritta

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

We

Dichiara sotto la propria responsabilità  
che il/i prodotto/i  
**Accessories and filling sets for TPN**

(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 V e VII  
della Direttiva 93/42/CEE**Classificazione**  
In accordo all'Allegato IX della Direttiva 93/42/CEE:  
Classe I sterile – Regola 1 / I sterile – Regola 2**Certificato CE Nr.**  
G2S 019717 0033 Rev. 00**Ente Notificato:**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 Monaco  
Germania

Nr. di identificazione 0123

**Data prima marcatura CE:**  
1998-04Doc #: 4/16-RA-cb  
Doc Rev #: 7.0

Rev date: 2021-01-11

Validità della dichiarazione:  
dal 2021-01-11  
fino al 2024-05-26hereby declare in our own responsibility  
that the product/s  
**Accessories and filling sets for TPN**

(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 V and VII  
of Council Directive 93/42/EEC**Classification**  
according to annex IX of Council Directive 93/42/EEC:  
Class I sterile – Rule 1 / I sterile – Rule 2**EC Certificate No.**  
G2S 019717 0033 Rev. 00**Notified body:**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 Munich  
Germany

Identification number 0123

**Date of first CE-marking:**  
1998-04Doc #: 4/16-RA-cb  
Doc Rev #: 7.0

Rev date: 2021-01-11

Validity of this declaration:  
from 2021-01-11  
until 2024-05-26

Mirandola, 11/04/2021

  
Francesco Benatti  
Managing Director

Mirandola, 11/01/2021

  
Dr. Giuliana Gavioli  
QM / RA Director

**Allegato I / Attachment I**

Nr. Art. / Art. No.	Descrizione Articolo / Article Description	Tipo / Type	Classe – Regola / Class – Rule
2112375	Female lock cap		I sterile – Rule 1
2112376	Non-reopening clamps		I sterile – Rule 1
2112516	Tamper resistant clamp		I sterile – Rule 1
2112517	Tamper resistant clamp		I sterile – Rule 1
2112016	Solu-care	Set per soluzione	I sterile – Rule 2
2112125	Evarex®	Secondary Module Circuit for Caretronic®	I sterile – Rule 2
2112250	Evarex®	Primary Module Circuit for Caretronic®	I sterile – Rule 2
2112433	Evarex®	2 - lead filling set	I sterile – Rule 2
2112447	Adapter male/male		I sterile – Rule 2
2112448	Adapter female/female		I sterile – Rule 2
2112449	Filling Sets for Nutrimix® DC		I sterile – Rule 2
2112468	3 Way Filling Set		I sterile – Rule 2
2112498	Transfer Set for Micro-Compounder N. 1	for use with Pinnacle TPN Management System	I sterile – Rule 2
2112499	Transfer Set for Micro-Compounder N.2	for use with Pinnacle TPN Management System	I sterile – Rule 2
2112501	6-Lead Transfer Set (Vented)		I sterile – Rule 2
2112502	9-Lead Transfer Set (Vented)		I sterile – Rule 2
2112503	6-Lead Transfer Set (Non Vented)		I sterile – Rule 2
2112504	9-Lead Transfer Set (Non Vented)		I sterile – Rule 2
2112514	Dual Chamber Bag Filling Set	for use with Pinnacle TPN Management System	I sterile – Rule 2
2112515	High Flow Y-Adapter Set		I sterile – Rule 2
2112519	9-Lead Transfer Set (Vented)	for use with Pinnacle TPN Management System with T connector for Micro-Compounder Set 1	I sterile – Rule 2
2112522	Universal Spike with FLL (Vented)		I sterile – Rule 2
2112523	Mini spike with FLL (Vented)		I sterile – Rule 2
2112554	Universal Spike	with Female Luer Lock (Vented)	I sterile – Rule 2
2112555	Mini Spike	with Female Luer Lock (Vented)	I sterile – Rule 2
2112605	Adapter Female / Male		I sterile – Rule 2
2124602	Paedifix N		I sterile – Rule 2
2124629	Anschlußleitung 0/3		I sterile – Rule 2
2129043	Nutriflex® transfer set		I sterile – Rule 2

Mirandola, 11/01/2021  
  
 Francesco Benatti  
 Managing Director

Mirandola, 11/01/2021  
  
 Dr. Giuliana Gavioli  
 QM / RA Director