

La sottoscritta

We

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO)
ItalyDichiara sotto la propria responsabilità
che il/i prodotto/i**Bags 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 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:

1998-04

Doc #: 5/16-RA-cb

Doc Rev #: 13.0

Rev date: 2021-04-20

Validità della dichiarazione:

dal 2021-04-20

fino al 2024-05-26

hereby declare in our own responsibility
that the product/s**Bags 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 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:

1998-04

Doc #: 5/16-RA-cb

Doc Rev #: 13.0

Rev date: 2021-04-20

Validity of this declaration:

from 2021-04-20

until 2024-05-26

Mirandola, *20/04/2021*
Francesco Benatti
Managing DirectorMirandola, *2021-04-20*
Chiara Bergamini
RA Director

Allegato I / Attachment I

| Nr. Art. / Art. No. | Descrizione Articolo / Article Description | Tipo / Type | Capaci- tà / Capaci- ty (ml) | Classe – Regola / Class - Rule |
|------------------------|---|--|---------------------------------------|--------------------------------------|
| 2112010 | Evarex® | Bag with three-way filling set and 50 µm filter | 3000 | II a – Rule 2 |
| 2112023 | Evarex® | Bag with three-way Filling Set | 2000 | II a – Rule 2 |
| 2112026 | Evarex® | Bag with three-way Filling set | 3000 | II a – Rule 2 |
| 2112027 | Evarex® | Bag with three-way filling set | 1000 | II a – Rule 2 |
| 2112060 | Infusionsmischbeutel | mit angeschraubtem Füllset aus EVA – 3000 ml | 3000 | II a – Rule 2 |
| 2112066 | Evarex® | Bag with three Tubings | 500 | II a – Rule 2 |
| 2112096 | Evarex® | Bag with three-way Filling Set and 50 µm Filter | 500 | II a – Rule 2 |
| 2112128 | Evarex® | Multilayer EVA/EVOH Bag with 40 µm Filter | 3000 | II a – Rule 2 |
| 2112129 | Evarex® | Bag for Caretronic® | 3000 | II a – Rule 2 |
| 2112141 | Evarex® | Multilayer EVA/EVOH Bag with Luer Lock | 500 | II a – Rule 2 |
| 2112142 | Evarex® | Multilayer EVA/EVOH Bag with Luer Lock | 1000 | II a – Rule 2 |
| 2112145 | NUTRIMIX® 0.2/0 | | 200 | II a – Rule 2 |
| 2112146 | NUTRIMIX® 0.5/0 | | 500 | II a – Rule 2 |
| 2112147 | NUTRIMIX® 1/0 | | 1000 | II a – Rule 2 |
| 2112150 | NUTRIMIX® 2/3 | | 2000 | II a – Rule 2 |
| 2112151 | NUTRIMIX® 3/3 | | 3000 | II a – Rule 2 |
| 2112176 | Evarex® | Multilayer EVA/EVOH Bag with Luer Lock | 2000 | II a – Rule 2 |
| 2112188 | Evarex® | Bag for Caretronic® | 1000 | II a – Rule 2 |
| 2112194 | Evarex® | Bag for Caretronic® | 2000 | II a – Rule 2 |
| 2112208 | Evarex® | Bag with three-way Filling Set | 500 | II a – Rule 2 |
| 2112227 | Evarex® | Bag with Filling Set | 250 | II a – Rule 2 |
| 2112228 | Evarex® | Bag with Filling Set | 500 | II a – Rule 2 |
| 2112229 | Evarex® | Bag with Filling Set | 1000 | II a – Rule 2 |
| 2112230 | Evarex® | Bag with Filling Set | 2000 | II a – Rule 2 |
| 2112231 | Evarex® | Bag with Filling Set | 3000 | II a – Rule 2 |
| 2112236 | Evarex® | Bag for Caretronic® | 500 | II a – Rule 2 |
| 2112237 | Evarex® | Bag for Caretronic® | 250 | II a – Rule 2 |
| 2112238 | Evarex® | two chamber bag for Caretronic® | 2500 + 500 | II a – Rule 2 |
| 2112249 | Evarex® | two Chamber Bag with a 3-way and a 1-way Filling Sets | 2500 + 500 | II a – Rule 2 |
| 2112281 | Evarex® | two Chamber Bag for Caretronic® | 1250+ 250 | II a – Rule 2 |
| 2112287 | NUTRIMIX® 3/0 | | 3000 | II a – Rule 2 |
| 2112295 | Evarex® | EVA Bag with Luer Lock | 250 | II a – Rule 2 |

Mirandola, 20/04/2021

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Managing Director

Mirandola, 2021-04-20

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|------------------------|---|--|---------------------------------------|--------------------------------------|
| 2112299 | Evarex® | Multilayer EVA/EVOH Bag with Luer Lock | 250 | II a – Rule 2 |
| 2112309 | Evarex® | EVA bag with Luer Lock | 1000 | II a – Rule 2 |
| 2112321 | NUTRIMIX® 0.5/3 | with filter 50 micron | 500 | II a – Rule 2 |
| 2112323 | NUTRIMIX® 3/3 | with filter 50 micron | 3000 | II a – Rule 2 |
| 2112335 | Evarex® | Multilayer EVA/EVOH Bag with 40 µm Filter | 5000 | II a – Rule 2 |
| 2112374 | Evarex® | Multilayer EVA/EVOH Bag with 6 Leads | 3000 | II a – Rule 2 |
| 2112377 | Evarex® | EVA infusion bag | 500 | II a – Rule 2 |
| 2112378 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 100 | II a – Rule 2 |
| 2112379 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 250 | II a – Rule 2 |
| 2112380 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 500 | II a – Rule 2 |
| 2112381 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 1000 | II a – Rule 2 |
| 2112382 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 2000 | II a – Rule 2 |
| 2112383 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 3000 | II a – Rule 2 |
| 2112384 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 100 | II a – Rule 2 |
| 2112386 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 500 | II a – Rule 2 |
| 2112387 | MIX BAG® EVA | Bolsa para Mistura de Solução Parenteral | 1000 | II a – Rule 2 |
| 2112413 | Evarex® | Multilayer EVA/EVOH Bag with 40µm Filter | 4000 | II a – Rule 2 |
| 2112414 | Evarex® | Multilayer EVA/EVOH Bag with 6 Leads | 4000 | II a – Rule 2 |
| 2112435 | Nutrimix® 0.2/0 | Kit with 5 bags | 200 | II a – Rule 2 |
| 2112436 | Nutrimix® 0.5/0 | Kit with 5 bags | 500 | II a – Rule 2 |
| 2112437 | Nutrimix® 1/0 | Kit with 5 bags | 1000 | II a – Rule 2 |
| 2112439 | Nutrimix® 3/0 | Kit with 5 bags | 3000 | II a – Rule 2 |
| 2112440 | Nutrimix® Barrier 0.2/0 | Kit with 5 bags | 200 | II a – Rule 2 |
| 2112441 | Nutrimix® Barrier 0.5/0 | Kit with 5 bags | 500 | II a – Rule 2 |
| 2112442 | Nutrimix® Barrier 1/0 | Kit with 5 bags | 1000 | II a – Rule 2 |
| 2112443 | Nutrimix® Barrier 2/0 | Kit with 5 bags | 2000 | II a – Rule 2 |
| 2112444 | Nutrimix® Barrier 3/0 | Kit with 5 bags | 3000 | II a – Rule 2 |
| 2112445 | Nutrimix® DC 1500 | / | 1250+ 250 | II a – Rule 2 |
| 2112446 | Nutrimix® DC 3000 | / | 2500+ 500 | II a – Rule 2 |
| 2112505 | EVA Mixing Container I | Kit with 5 bags For use with Pinnacle TPN Management System | 250 ml | II a – Rule 2 |
| 2112506 | EVA Mixing Container | Kit with 5 bags For use with Pinnacle TPN Management System | 500 | II a – Rule 2 |
| 2112507 | EVA Mixing Container | Kit with 5 bags For use with Pinnacle TPN Management System | 1000 | II a – Rule 2 |

Mirandola, 20/04/2021

Francesco Benatti
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|------------------------|---|--|---------------------------------------|--------------------------------------|
| 2112508 | EVA Mixing Container | Kit with 5 bags For use with Pinnacle TPN Management System | 2000 | II a – Rule 2 |
| 2112509 | EVA Mixing Container | Kit with 5 bags For use with Pinnacle TPN Management System | 3000 | II a – Rule 2 |
| 2112510 | EVA Mixing Container | Kit with 5 bags For use with Pinnacle TPN Management System | 4000 | II a – Rule 2 |
| 2112511 | EVA Dual Chamber Mixing Container | Kit with 7 bags For use with Pinnacle TPN Management System | 1250 + 250 | II a – Rule 2 |
| 2112512 | EVA Dual Chamber Mixing Container | Kit with 7 bags For use with Pinnacle TPN Management System | 2500 + 500 | II a – Rule 2 |
| 2112513 | EVA Dual Chamber Mixing Container | Kit with 7 bags For use with Pinnacle TPN Management System | 3500 + 500 | II a – Rule 2 |
| 2112520 | Evarex® | 150 ml Bag | 150 | II a – Rule 2 |
| 2112521 | Evarex® | 250 ml Bag | 250 | II a – Rule 2 |
| 2112546 | EVA Mixing Container | For use with Pinnacle TPN Management System | 250 | II a – Rule 2 |
| 2112547 | EVA Mixing Container | For use with Pinnacle TPN Management System | 500 | II a – Rule 2 |
| 2112548 | EVA Mixing Container | For use with Pinnacle TPN Management System | 1000 | II a – Rule 2 |
| 2112549 | EVA Mixing Container | For use with Pinnacle TPN Management System | 2000 | II a – Rule 2 |
| 2112552 | EVA Mixing Container | For use with Pinnacle TPN Management System | 3000 | II a – Rule 2 |
| 2112553 | EVA Mixing Container | For use with Pinnacle TPN Management System | 4000 | II a – Rule 2 |
| 2112564 | EVA Dual Chamber Mixing Container | For use with Pinnacle TPN Management System | 500 | II a – Rule 2 |
| 2112606 | EVA Mixing Container | For use with Pinnacle TPN Management System | 1250 + 250 | II a – Rule 2 |
| 2112607 | EVA Mixing Container | For use with Pinnacle TPN Management System | 2500+ 500 | II a – Rule 2 |
| 2112608 | EVA Mixing Container | For use with Pinnacle TPN Management System | 3500+ 500 | II a – Rule 2 |

Mirandola, 29/04/2021

Francesco Benatti
Managing Director

Mirandola, 20/04/2021

Chiara Bergamini
RA Director