

Nous

We

**B. BRAUN MEDICAL SAS
SRN FR-MF-00000674**26 Rue Armengaud
92210 Saint-Cloud
FRANCEdéclarons par les présentes et sous notre seule
responsabilité que le/les produit/s

Basic-UDI-DI (voir annexe I)

Flexima® 3SDestination : **Recueil et stockage des selles ou de l'urine par les
patients ayant subi une entérostomie et/ou une urostomie.
Le produit peut être utilisé sur une peau intacte ou présentant
des lésions.**

(numéros d'article voir annexe I)

Fabriqué à
B.BRAUN MEDICAL SAS
Z.I. de Layats, 64500 Saint-Jean-de-Luz, FRANCEest / sont conforme(s) aux exigences du Règlement
(UE) 2017/745 relatif aux dispositifs médicaux amendé
par le Règlement (UE) 2020/561**Procédure d'évaluation de la conformité**
selon l'annexe IV
du Règlement mentionné ci-dessus**Classification**
conformément à l'annexe VIII du Règlement
susmentionné : (voir Annexe I)**Date du premier marquage CE
ou premier numéro de lot**
2012-09**Valable jusqu'au**
2026-12-31Saint-Jean-de-Luz, *See Date of B.DoCS Signature*
Name/Position: Riccardo Arico
Site Director*See B.DoCS signature page*hereby declare under our own responsibility that the
product/s

Basic-UDI-DI (see attachment I)

Flexima® 3SIntended purpose: **Collection and containment of stools or urine
by patients with an enterostomy and/or urostomy.
The product can be used on intact and injured skin.**

(article numbers see attachment I)

Manufactured in
B.BRAUN MEDICAL SAS
Z.I. de Layats, 64500 Saint-Jean-de-Luz, Franceis/are in compliance with the requirements of the Medical
Device Regulation (EU) 2017/745 amended by Regulation
(EU) 2020/561**Conformity Assessment Procedure**
according to annex IV
of the Regulation named above**Classification**
according to annex VIII of the Regulation named above:
(See Attachment I)**Date of first EC-marking
or first lot number**
2012-09**Valid until**
2026-12-31Saint-Cloud, *See Date of B.DoCS Signature*
Name / Position: Emmanuel Da Silva
Quality Manager - PRRC*See B.DoCS signature page*

Annexe I / Attachment I

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
936415L	Flexima® 3S Standard Base Plate diameter 45 mm cut-to- fit 15-30 mm	Not Applicable	I	N	4039239000000116ZG
936420L	Flexima® 3S Standard Base Plate diameter 45 mm precut 20 mm	Not Applicable	I	N	4039239000000116ZG
936425L	Flexima® 3S Standard Base Plate diameter 45 mm precut 25 mm	Not Applicable	I	N	4039239000000116ZG
936430L	Flexima® 3S Standard Base Plate diameter 45 mm precut 30 mm	Not Applicable	I	N	4039239000000116ZG
936515L	Flexima® 3S Standard Base Plate diameter 55 mm cut-to- fit 15-40 mm	Not Applicable	I	N	4039239000000116ZG
936535L	Flexima® 3S Standard Base Plate diameter 55 mm precut 35 mm	Not Applicable	I	N	4039239000000116ZG
936540L	Flexima® 3S Standard Base Plate diameter 55 mm precut 40 mm	Not Applicable	I	N	4039239000000116ZG
936615L	Flexima® 3S Standard Base Plate diameter 65 cut-to-fit 15-50 mm	Not Applicable	I	N	4039239000000116ZG
936645L	Flexima® 3S Standard Base Plate diameter 65 mm precut 45 mm	Not Applicable	I	N	4039239000000116ZG
936815L	Flexima® 3S Standard Base Plate diameter 80 mm cut- to-fit 15-65 mm	Not Applicable	I	N	4039239000000116ZG
937415L	Flexima® 3S Base Plate Convex diameter 45 mm cut- to-fit 15-26mm	Not Applicable	I	N	4039239000000117ZJ
937425L	Flexima® 3S Base Plate Convex diameter 45 mm precut 25 mm	Not Applicable	I	N	4039239000000117ZJ
937515L	Flexima® 3S Base Plate Convex diameter 55 mm cut- to-fit 15-36 mm	Not Applicable	I	N	4039239000000117ZJ
937530L	Flexima® 3S Base Plate Convex diameter 55 mm precut 30 mm	Not Applicable	I	N	4039239000000117ZJ
937615L	Flexima® 3S Base Plate Convex diameter 65 mm cut- to-fit 15-46 mm	Not Applicable	I	N	4039239000000117ZJ

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
931045L	Flexima® 3S Closed pouch Midi Beige diameter 45 mm	Not Applicable	I	N	403923900000121Z9
931055L	Flexima® 3S Closed pouch Midi Beige diameter 55 mm	Not Applicable	I	N	403923900000121Z9
931065L	Flexima® 3S Closed pouch Midi Beige diameter 65 mm	Not Applicable	I	N	403923900000121Z9
931445L	Flexima® 3S Closed pouch Maxi Beige diameter 45 mm	Not Applicable	I	N	403923900000121Z9
931455L	Flexima® 3S Closed pouch Maxi Beige diameter 55 mm	Not Applicable	I	N	403923900000121Z9
931465L	Flexima® 3S Closed pouch Maxi Beige diameter 65 mm	Not Applicable	I	N	403923900000121Z9
931480L	Flexima® 3S Closed pouch Maxi Beige diameter 80 mm	Not Applicable	I	N	403923900000121Z9
931545L	Flexima® 3S Closed pouch Maxi Transparent diameter 45 mm	Not Applicable	I	N	403923900000121Z9
931555L	Flexima® 3S Closed pouch Maxi Transparent diameter 55 mm	Not Applicable	I	N	403923900000121Z9
931565L	Flexima® 3S Closed pouch Maxi Transparent diameter 65 mm	Not Applicable	I	N	403923900000121Z9
931580L	Flexima® 3S Closed pouch Maxi Transparent diameter 80 mm	Not Applicable	I	N	403923900000121Z9
932045L	Flexima® 3S drainable Roll'Up Midi Beige diameter 45 mm	Not Applicable	I	N	403923900000122ZB
932055L	Flexima® 3S drainable Roll'Up Midi Beige diameter 55 mm	Not Applicable	I	N	403923900000122ZB
932065L	Flexima® 3S drainable Roll'Up Midi Beige diameter 65 mm	Not Applicable	I	N	403923900000122ZB
932145L	Flexima® 3S drainable Roll'Up Midi Transparent diameter 45 mm	Not Applicable	I	N	403923900000122ZB
932155L	Flexima® 3S drainable Roll'Up Midi Transparent diameter 55 mm	Not Applicable	I	N	403923900000122ZB
932165L	Flexima® 3S drainable Roll'Up Midi Transparent diameter 65 mm	Not Applicable	I	N	403923900000122ZB
932445L	Flexima® 3S drainable Roll'Up Maxi Beige diameter 45 mm	Not Applicable	I	N	403923900000122ZB
932455L	Flexima® 3S drainable Roll'Up Maxi Beige diameter 55 mm	Not Applicable	I	N	403923900000122ZB
932465L	Flexima® 3S drainable Roll'Up Maxi Beige diameter 65 mm	Not Applicable	I	N	403923900000122ZB

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
932480L	Flexima® 3S drainable Roll'Up Maxi Beige diameter 80 mm	Not Applicable	I	N	4039239000000122ZB
932545L	Flexima® 3S drainable Roll'Up Maxi Transparent diameter 45 mm	Not Applicable	I	N	4039239000000122ZB
932555L	Flexima® 3S drainable Roll'Up Maxi Transparent diameter 55 mm	Not Applicable	I	N	4039239000000122ZB
932565L	Flexima® 3S drainable Roll'Up Maxi Transparent diameter 65 mm	Not Applicable	I	N	4039239000000122ZB
932580L	Flexima® 3S drainable Roll'Up Maxi Transparent diameter 80 mm	Not Applicable	I	N	4039239000000122ZB
933055L	Flexima® 3S drainable High Flow Beige with inspection window diameter 55 mm	Not Applicable	I	N	4039239000000123ZD
933065L	Flexima® 3S drainable High Flow Beige with inspection window diameter 65 mm	Not Applicable	I	N	4039239000000123ZD
933080L	Flexima® 3S drainable High Flow Beige with inspection window diameter 80 mm	Not Applicable	I	N	4039239000000123ZD
933155L	Flexima® 3S drainable High Flow Transparent diameter 55 mm	Not Applicable	I	N	4039239000000123ZD
933165L	Flexima® 3S drainable High Flow Transparent diameter 65 mm	Not Applicable	I	N	4039239000000123ZD
933180L	Flexima® 3S drainable High Flow Transparent diameter 80 mm	Not Applicable	I	N	4039239000000123ZD
934045L	Flexima® 3S urostomy Midi Beige with inspection window diameter 45 mm	Not Applicable	I	N	4039239000000124ZF
934055L	Flexima® 3S urostomy Midi Beige with inspection window diameter 55 mm	Not Applicable	I	N	4039239000000124ZF
934065L	Flexima® 3S urostomy Midi Beige with inspection window diameter 65 mm	Not Applicable	I	N	4039239000000124ZF
934145L	Flexima® 3S urostomy Midi Transparent diameter 45 mm	Not Applicable	I	N	4039239000000124ZF
934155L	Flexima® 3S urostomy Midi Transparent diameter 55 mm	Not Applicable	I	N	4039239000000124ZF
934165L	Flexima® 3S urostomy Midi Transparent diameter 65 mm	Not Applicable	I	N	4039239000000124ZF

Annexe II / Attachment II: Spécifications communes/ Common specifications

Not applicable

Document amendment information

Version	Description of the changes
1.0	Initial creation as per MDR
2.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

Title: Flexima 3S - Déclaration EU conformité MDR - Portugal Initiator: Sylvie Massenat

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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