

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® & Flexima® Uro SilkDestination : **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**
2003-01**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® & Flexima® Uro SilkIntended 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**
2003-01**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
044015L	Flexima® closed pouches Midi Beige cut-to-fit 15-60 mm	Not Applicable	I	N	4039239000000103Z7
044025L	Flexima® closed pouches Midi Beige precut 25 mm	Not Applicable	I	N	4039239000000103Z7
044030L	Flexima® closed pouches Midi Beige precut 30 mm	Not Applicable	I	N	4039239000000103Z7
044035L	Flexima® closed pouches Midi Beige precut 35 mm	Not Applicable	I	N	4039239000000103Z7
044040L	Flexima® closed pouches Midi Beige precut 40 mm	Not Applicable	I	N	4039239000000103Z7
044045L	Flexima® closed pouches Midi Beige precut 45 mm	Not Applicable	I	N	4039239000000103Z7
044070L	Flexima® closed pouches Maxi Beige with inspection window cut-to-fit 15-75 mm	Not Applicable	I	N	4039239000000103Z7
044170L	Flexima® closed pouches Maxi Transparent cut-to-fit 15-75 mm	Not Applicable	I	N	4039239000000103Z7
44212L	Flexima® closed pouches Mini Beige cut-to-fit 15-45 mm	Not Applicable	I	N	4039239000000103Z7
44018L	Flexima® convex closed pouches Midi Beige cut-to-fit 15-45 mm	Not Applicable	I	N	4039239000000104Z9
44118L	Flexima® convex closed pouches Midi Transparent cut-to-fit 15-45 mm	Not Applicable	I	N	4039239000000104Z9
42716L	Flexima® drainable Roll'Up pouches Midi Split Cover cut- to-fit 15-60 mm	Not Applicable	I	N	4039239000000105ZB
42715L	Flexima® drainable Roll'Up pouches Midi Beige cut-to-fit 15-60 mm	Not Applicable	I	N	4039239000000105ZB
42815L	Flexima® drainable Roll'Up pouches Midi Transparent cut-to-fit 15-60 mm	Not Applicable	I	N	4039239000000105ZB

Effective

BBMF-M-5-2-01-004-2_2.0

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
42725L	Flexima® drainable Roll'Up pouches Midi Beige precut 25 mm	Not Applicable	I	N	4039239000000105ZB
42730L	Flexima® drainable Roll'Up pouches Midi Beige precut 30 mm	Not Applicable	I	N	4039239000000105ZB
42735L	Flexima® drainable Roll'Up pouches Midi Beige precut 35 mm	Not Applicable	I	N	4039239000000105ZB
42740L	Flexima® drainable Roll'Up pouches Midi Beige precut 40 mm	Not Applicable	I	N	4039239000000105ZB
42718L	Flexima® drainable Roll'Up Convex pouches Midi Beige cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000019427
42818L	Flexima® drainable Roll'Up Convex pouches Midi Transparent cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000019427
42776L	Flexima® drainable Roll'Up pouches Maxi Split Cover cut- to-fit 15-76 mm	Not Applicable	I	N	4039239000000105ZB
044913L	Flexima® Uro Silk Urostomy pouches Midi Transparent cut-to-fit 12-55 mm	Not Applicable	I	N	4039239000000107ZF
044914L	Flexima® Uro Silk Urostomy pouches Midi Beige cut-to-fit 12-55 mm	Not Applicable	I	N	4039239000000107ZF
44919L	Flexima® Uro Silk convex urostomy pouches Midi Beige cut-to-fit 15-35 mm	Not Applicable	I	N	4039239000000108ZH

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-FR09-409: Creation of Portugal references (42716L and 42776L).
3.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

Title: Flexima 1P - 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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