

Nous

We

B. BRAUN MEDICAL SAS
SRN FR-MF-000000674
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® ActiveDestination : **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**
2009-11**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® ActiveIntended 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**
2009-11**Valid until**
2026-12-31Saint-Cloud, *See Date of B.DoCS Signature*
Name: 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
4612215L	Flexima® Active closed pouches Mini Beige with inspection window cut-to-fit 15-45	Not Applicable	I	N	4039239000000992C
4612115L	Flexima® Active closed pouches Midi Beige with inspection window cut-to-fit 15-50 mm	Not Applicable	I	N	4039239000000992C
4612380L	Flexima® Active closed pouches Maxi Beige with inspection window cut-to-fit 15-65 mm	Not Applicable	I	N	4039239000000992C
4612716L	Flexima® Active, 1-piece closed bag, Midi, Soft Convex, cut-to-fit 15-45 mm, Beige with split cover	Not Applicable	I	N	40392390000029283G
4622215L	Flexima® Active drainable Roll'Up pouches Mini Beige with inspection window cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000100YZ
4622716L	Flexima® Active drainable Roll'Up pouches Midi Beige with inspection window cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000101Z3
4622115L	Flexima® Active drainable Roll'Up pouches Midi Beige with inspection window cut-to-fit 15-50 mm	Not Applicable	I	N	403923900000100YZ
4621716L	Flexima® Active drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000101Z3
4622717L	Flexima® Active drainable Roll'Up pouches Maxi Beige with inspection window cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000101Z3
4622380L	Flexima® Active drainable Roll'Up pouches Maxi Beige with inspection window cut-to-fit 15-65 mm	Not Applicable	I	N	403923900000100YZ
4622715L	Flexima® Active, 1-piece Roll'up drainable bag, Maxi, Soft Convex, cut-to-fit 15-35 mm, Beige with split cover	Not Applicable	I	N	403923900000101Z3
4632716L	Flexima® Active, 1-piece high flow bag, Soft Convex, cut-to-fit 15-45 mm, Beige with split cover	Not Applicable	I	N	40392390000029293J
4641715L	Flexima® Active urostomy pouches Midi Transparent cut-to-fit 15-35 mm	Not Applicable	I	N	403923900000102Z5

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
4642715L	Flexima® Active, 1-piece urostomy bag, Midi, Soft Convex, cut-to-fit 15-35 mm, Beige with split cover, with connector	Not Applicable	I	N	4039239000000102Z5
4642725L	Flexima® Active, 1-piece urostomy bag, Midi, Soft Convex, pre-cut 25 mm, Beige with split cover, with connector	Not Applicable	I	N	4039239000000102Z5
4642730L	Flexima® Active, 1-piece urostomy bag, Midi, Soft Convex, pre-cut 30 mm, Beige with split cover, with connector	Not Applicable	I	N	4039239000000102Z5

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	Subrange of the device has been removed from the DoC so that only the designation and trade name of the device are included to allow a better identification of the product.
3.0	CC OM-CHC-FR09-409: Creation of Portugal references (4612215L, 4612115L, 4612380L, 4622215L, 4622115L and 4622380L).
4.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

Title: Flexima Active - 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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