

Nous

We

B. BRAUN MEDICAL SAS**SRN FR-MF-00000674**

26 Rue Armengaud

92210 Saint-Cloud

FRANCE

déclarons par les présentes et sous notre seule
responsabilité que le/les produit/s

Basic-UDI-DI (voir annexe I)

**Flexima®-Softima® Active /
Flexima®-Softima® Active O Convex**Destination : **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, FRANCE

est / 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

2026-12-31

Saint-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®-Softima® Active /
Flexima®-Softima® Active O Convex**Intended 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, France

is/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

2026-12-31

Saint-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
4610125	Flexima®-Softima® Active closed pouches Midi Beige with inspection window precut 25 mm by 30 units	Not Applicable	I	N	40392390000000992C
4610130	Flexima®-Softima® Active closed pouches Midi Beige with inspection window precut 30 mm by 30 units	Not Applicable	I	N	40392390000000992C
4610135	Flexima®-Softima® Active closed pouches Midi Beige with inspection window precut 35 mm by 30 units	Not Applicable	I	N	40392390000000992C
4610140	Flexima®-Softima® Active closed pouches Midi Beige with inspection window precut 40 mm by 30 units	Not Applicable	I	N	40392390000000992C
4611115	Flexima®-Softima® Active closed pouches Midi Transparent cut-to-fit 15-50 mm by 30 units	Not Applicable	I	N	40392390000000992C
4611380	Flexima®-Softima® Active closed pouches Maxi Transparent cut-to-fit 15-65 mm by 30 units	Not Applicable	I	N	40392390000000992C
4612215	Flexima®-Softima® Active closed pouches Mini Beige with inspection window cut-to-fit 15-45 mm by 30 units	Not Applicable	I	N	40392390000000992C
4612115	Flexima®-Softima® Active closed pouches Midi Beige with inspection window cut-to-fit 15-50 mm by 30 units	Not Applicable	I	N	40392390000000992C
4612115X1	Sample Flexima®-Softima® Active closed Bag Midi Split Cover cut-to-fit 15-50 mm	Not Applicable	I	N	40392390000000992C
4612380	Flexima®-Softima® Active closed pouches Maxi Beige with inspection window cut-to-fit 15-65 mm by 30 units	Not Applicable	I	N	40392390000000992C
4620215	Flexima®-Softima® Active drainable Roll'Up pouches Mini Beige cut-to-fit 15-45 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4621215	Flexima®-Softima® Active drainable Roll'Up pouches Mini Transparent cut-to-fit 15-45 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
4620115	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige cut-to-fit 15-50 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4620125	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 25 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4620130	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 30 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4620135	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 35 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4620140	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 40 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4621115	Flexima®-Softima® Active drainable Roll'Up pouches Midi Transparent cut-to-fit 15-50 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4620380	Flexima®-Softima® Active drainable Roll'Up pouches Maxi Beige cut-to-fit 15-65 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4621380	Flexima®-Softima® Active drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-65 mm by 10, 30 units	Not Applicable	I	N	4039239000000100YZ
4622215	Flexima®-Softima® Active drainable Roll'Up pouches Mini Beige with inspection window cut-to-fit 15-45 mm by 30 units	Not Applicable	I	N	4039239000000100YZ
4622115	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige with inspection window cut-to-fit 15-50 mm by 30 units	Not Applicable	I	N	4039239000000100YZ
4622115X1	Sample Flexima®-Softima® Active drainable Roll'Up bag Midi Split Cover cut-to-fit 15-50 mm	Not Applicable	I	N	4039239000000100YZ
4622380	Flexima®-Softima® Active drainable Roll'Up pouches Maxi Beige with inspection window cut-to-fit 15-65 mm by 30 units	Not Applicable	I	N	4039239000000100YZ
4612716	Flexima®-Softima® Active O'Convex, 1-piece closed bag, Midi, Soft Convex, cut-to-fit 15-45 mm, Beige with split cover, by 10 units	Not Applicable	I	N	403923900000029283G

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
4621716	Flexima®-Softima® Active O Convex drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000101Z3
4622715	Flexima®-Softima® Active O'Convex, 1-piece Roll'up drainable bag, Maxi, Soft Convex, cut-to-fit 15-35 mm, Beige with split cover, by 10 units	Not Applicable	I	N	403923900000101Z3
4622716	Flexima®-Softima® Active O Convex drainable Roll'Up pouches Midi Beige with inspection window cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000101Z3
4622717	Flexima®-Softima® Active O Convex drainable Roll'Up pouches Maxi Beige with inspection window cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000101Z3
4622717X1	Sample Flexima®-Softima® Active O Convex drainable Roll'Up bag Maxi Split Cover cut-to-fit 15-45 mm	Not Applicable	I	N	403923900000101Z3
4632716	Flexima®-Softima® Active O'Convex, 1-piece high flow bag, Soft Convex, cut-to-fit 15-45 mm, Beige with split cover, by 10 units	Not Applicable	I	N	40392390000029293J
4641715	Flexima®-Softima® Active O Convex urostomy pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000102Z5
4641715X1	Sample Flexima®-Softima® Active O Convex urostomy bag Midi Transparent cut-to-fit 15-35 mm	Not Applicable	I	N	403923900000102Z5
4642715	Flexima®-Softima® Active O'Convex, 1-piece urostomy bag, Midi, Soft Convex, cut-to-fit 15-35 mm, Beige with split cover, with connector, by 10 units	Not Applicable	I	N	403923900000102Z5
4642725	Flexima®-Softima® Active O'Convex, 1-piece urostomy bag, Midi, Soft Convex, pre-cut 25 mm, Beige with split cover, with connector, by 10 units	Not Applicable	I	N	403923900000102Z5

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
4642730	Flexima®-Softima® Active O'Convex, 1-piece urostomy bag, Midi, Soft Convex, pre-cut 30 mm, Beige with split cover, with connector, by 10 units	Not Applicable	I	N	403923900000102Z5
4620115D	Flexima® Active Set drainable pouches Roll'Up Midi Beige cut-to-fit 15-50 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV
4620125D	Flexima® Active Set drainable pouches Roll'Up Midi Beige precut 25 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV
4620130D	Flexima® Active Set drainable pouches Roll'Up Midi Beige precut 30 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV
4620135D	Flexima® Active Set drainable pouches Roll'Up Midi Beige precut 35 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV
4620140D	Flexima® Active Set drainable pouches Roll'Up Midi Beige precut 40 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV
4621115D	Flexima® Active Set drainable pouches Roll'Up Midi Transparent cut-to-fit 15-50 mm + adhesive rings for Spain by 30 units	Not Applicable	I	N	4039239000002124ZV

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	New template (version 2) Update of date of validity as per # 218149
3.0	Edition as per ISO 13485 certificate No Q5 022239 0094 Rev. 02
4.0	Update of date of validity as per #313578
5.0	CC OM-CHC-FR09-272 - Creation of new references Active O'Convex (4612716, 4622715, 4632716, 4642715, 4642725, 4642730). Update of date of validity as per #313578
6.0	CC OM-CHC-FR09-314 : Creation of sample box reference (4612115X1, 4622115X1, 4622717X1, 4641715X1)
7.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

Title: Déclaration EU conformité MDR - Flexima-Softima Active 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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