

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 : Poches de recueil 1-pièce planes fermées,
vidables Roll'Up et convexes vidables Roll'Up et urostomie
(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**
2023-12-31Saint-Jean-de-Luz, *See Date of B.DoCS Signature*
Name: Laurent Buono
Function: 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: 1-piece flat closed, drainable Roll'Up and
convex Drainable Roll'Up and urostomy collection pouches
(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**
2023-12-31Saint-Cloud, *See Date of B.DoCS Signature*
Name: Manuelle Schneider-Ponsot
Function: Regulatory and Scientific Affairs Director*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
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
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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
4620130	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 30 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
4620135	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 35 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
4620140	Flexima®-Softima® Active drainable Roll'Up pouches Midi Beige precut 40 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
4621115	Flexima®-Softima® Active drainable Roll'Up pouches Midi Transparent cut-to-fit 15-50 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
4620380	Flexima®-Softima® Active drainable Roll'Up pouches Maxi Beige cut-to-fit 15-65 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
4621380	Flexima®-Softima® Active drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-65 mm by 10, 30 units	Not Applicable	I	N	403923900000100YZ
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	403923900000100YZ
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	403923900000100YZ
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	403923900000100YZ
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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
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
4641715	Flexima®-Softima® Active 0 Convex urostomy pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	4039239000000102Z5
4621716	Flexima®-Softima® Active 0 Convex drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	4039239000000101Z3
4622716	Flexima®-Softima® Active 0 Convex drainable Roll'Up pouches Midi Beige with inspection window cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	4039239000000101Z3
4622717	Flexima®-Softima® Active 0 Convex drainable Roll'Up pouches Maxi Beige with inspection window cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	4039239000000101Z3

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

Title: Déclaration CE 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:

UserName: Desplat, Isabelle (despisfr)
Title: Regulatory Affairs Officer
Date: Tuesday, 06 July 2021, 10:32 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Buono, Laurent (buonlafr)
Title: Site Director
Date: Tuesday, 06 July 2021, 10:57 W. Europe Daylight Time
Meaning: Approve Document

UserName: Schneider-Ponsot, Manuelle (schnmafr)
Title: Quality Director / Safety Officer / Resp Pharmacist
Date: Tuesday, 06 July 2021, 17:37 W. Europe Daylight Time
Meaning: Approve Document
