

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®-Softima® & Flexima®-Softima® Uro SilkDestination : Poches de recueil 1-pièce planes et convexes
fermées, vidable Roll'Up, Haut Débit et Urostomie
(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**
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®-Softima® & Flexima®-Softima® Uro SilkIntended purpose: 1-piece collection pouches flat & convex
closed, drainable Roll'Up & High Flow and Urostomy
(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**
2003-01**Valid until**
2026-12-31Saint-Cloud, *See Date of B.DoCS Signature*Name / Position: Manuelle Schneider-Ponsot
Director of Regulatory and Pharmaceutical Operation
Safety Officer*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
044015	Flexima®-Softima® closed pouches Midi Beige cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044025	Flexima®-Softima® closed pouches Midi Beige precut 25 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044030	Flexima®-Softima® closed pouches Midi Beige precut 30 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044035	Flexima®-Softima® closed pouches Midi Beige precut 35 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044040	Flexima®-Softima® closed pouches Midi Beige precut 40 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044045	Flexima®-Softima® closed pouches Midi Beige precut 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044070	Flexima®-Softima® closed pouches Maxi Beige with inspection window cut-to-fit 15-75 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044115	Flexima®-Softima® closed pouches Midi Transparent cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044170	Flexima®-Softima® closed pouches Maxi Transparent cut-to-fit 15-75 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
44212	Flexima®-Softima® closed pouches Mini Beige cut-to-fit 15-45 mm by 30 units	Not Applicable	I	N	4039239000000103Z7
44220	Flexima®-Softima® closed pouches Mini Beige precut 20 mm by 30 units	Not Applicable	I	N	4039239000000103Z7
44225	Flexima®-Softima® closed pouches Mini Beige precut 25 mm by 30 units	Not Applicable	I	N	4039239000000103Z7

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
44230	Flexima®-Softima® closed pouches Mini Beige precut 30 mm by 30 units	Not Applicable	I	N	4039239000000103Z7
44235	Flexima®-Softima® closed pouches Mini Beige precut 35 mm by 30 units	Not Applicable	I	N	4039239000000103Z7
M44015D	Flexima® closed pouches Midi Beige cut-to-fit 15-60 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44025D	Flexima® closed pouches Midi Beige precut 25 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44030D	Flexima® closed pouches Midi Beige precut 30 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44035D	Flexima® closed pouches Midi Beige precut 35 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44040D	Flexima® closed pouches Midi Beige precut 40 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44045D	Flexima® closed pouches Midi Beige precut 45 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	4039239000000103Z7
M44070D	Flexima® closed pouches Maxi Beige cut-to-fit 15-75 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	40392390000014872Y
M44115D	Flexima® closed pouches Midi Transparent cut-to-fit 15-60 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	40392390000014872Y

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
M44170D	Flexima® closed pouches Maxi Transparent cut-to-fit 15-75 mm with micropore rings for Spain by 30 units	Not Applicable	I	N	40392390000014872Y
44017	Flexima®-Softima® convex closed pouches Midi Beige cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	4039239000000104Z9
44018	Flexima®-Softima® convex closed pouches Midi Beige cut-to-fit 15-45 mm by 10 or 30 units	Not Applicable	I	N	4039239000000104Z9
44031	Flexima®-Softima® convex closed pouches Midi Beige precut 30 mm by 10 units	Not Applicable	I	N	4039239000000104Z9
44037	Flexima®-Softima® convex closed pouches Midi Beige precut 35 mm by 10 units	Not Applicable	I	N	4039239000000104Z9
44117	Flexima®-Softima® convex closed pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	4039239000000104Z9
44118	Flexima®-Softima® convex closed pouches Midi Transparent cut-to-fit 15-45 mm by 10 or 30 units	Not Applicable	I	N	4039239000000104Z9
42970	Flexima®-Softima® drainable High flow pouches Beige cut- to-fit 15-76 mm by 10, 30 units	Not Applicable	I	N	4039239000000106ZD
42971	Flexima®-Softima® drainable High flow pouches Transparent cut-to-fit 15-76 mm by 10, 30 units	Not Applicable	I	N	4039239000000106ZD
42710	Flexima®-Softima® drainable Roll'Up pouches Mini Split Cover cut-to-fit 15-45 mm by 30- units	Not Applicable	I	N	4039239000000105ZB

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
42716	Flexima®-Softima® drainable Roll'Up pouches Midi Split Cover cut-to-fit 15-60 mm by 30 units	Not Applicable	I	N	403923900000105ZB
42715	Flexima®-Softima® drainable Roll'Up pouches Midi Beige cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42815	Flexima®-Softima® drainable Roll'Up pouches Midi Transparent cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42725	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 25 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42730	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 30 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42735	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 35 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42740	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 40 mm by 10, 30 units	Not Applicable	I	N	403923900000105ZB
42776	Flexima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-76 mm by 30 units	Not Applicable	I	N	403923900000105ZB
42776DE	Softima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-75 mm for Germany by 30 units	Not Applicable	I	N	403923900000105ZB
42776E	Softima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-75 mm for Ireland and UK by 30 units	Not Applicable	I	N	403923900000105ZB
42776K	Softima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-75 mm for Netherlands by 30 units	Not Applicable	I	N	403923900000105ZB

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
42876	Flexima® drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-76 mm by 30 units	Not Applicable	I	N	403923900000105ZB
42876E	Softima® drainable Roll'Up pouches Maxi Transparent cut-to-fit 15-75 mm for Ireland and UK by 30 units	Not Applicable	I	N	403923900000105ZB
42715D	Set Flexima® drainable Roll'Up pouches Midi Beige cut-to-fit 15-60 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42815D	Set Flexima® drainable Roll'Up pouches Midi Transparent cut-to-fit 15-60 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42725D	Set Flexima® drainable Roll'Up pouches Midi Beige precut 25 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42730D	Set Flexima® drainable Roll'Up pouches Midi Beige precut 30 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42735D	Set Flexima® drainable Roll'Up pouches Midi Beige precut 35 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42740D	Set Flexima® drainable Roll'Up pouches Midi Beige precut 40 mm + Micropore rings for Spain by 30 units	Not Applicable	I	N	403923900000148832
42717	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Beige cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000019427
42718	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Beige cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000019427

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
42719	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Split Cover cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000019427
42720	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Split Cover cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000019427
42726	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Beige precut 25 mm by 10 units	Not Applicable	I	N	403923900000019427
42731	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Beige precut 30 mm by 10 units	Not Applicable	I	N	403923900000019427
42817	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000019427
42818	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Transparent cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	403923900000019427
044913	Flexima®-Softima® Uro Silk Urostomy pouches Midi Transparent cut-to-fit 12-55 mm by 10, 20 or 30 units	Not Applicable	I	N	4039239000000107ZF
044914	Flexima®-Softima® Uro Silk Urostomy pouches Midi Beige cut-to-fit 12-55 mm by 10, 20 or 30 units	Not Applicable	I	N	4039239000000107ZF
44820	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 20 mm by 30 units	Not Applicable	I	N	4039239000000107ZF
44825	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 25 mm by 30 units	Not Applicable	I	N	4039239000000107ZF
44830	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 30 mm by 30 units	Not Applicable	I	N	4039239000000107ZF

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
44836	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 35 mm by 30 units	Not Applicable	I	N	403923900000107ZF
044913AA	Flexima® Uro Silk Urostomy pouches Midi Transparent cut-to-fit 12-55 mm with 5 Connector Uro for Argentina by 10+5 units (10 pouches + 5 connector)	Not Applicable	I	N	403923900000107ZF
044913D	Set Flexima® Uro Silk Urostomy pouches Midi Transparent cut-to-fit 12-55 mm + 30 Micropores Rings for Spain by 30 units	Not Applicable	I	N	403923900000148934
44915	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent cut-to-fit 15-25 mm by 10 units	Not Applicable	I	N	403923900000108ZH
44917	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000108ZH
44919	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Beige cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	403923900000108ZH
44920	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent precut 25 mm by 10 units	Not Applicable	I	N	403923900000108ZH
44922	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent precut 30 mm by 10 units	Not Applicable	I	N	403923900000108ZH

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	Addition of 044670, 44017, 43017, 44117, 43117, 44018, 43018, 44118, 43118, 44031, 43031, 44037, 43037
3.0	Addition of 044015, 044025, 044030, 044035, 044040, 044045, 044115, 044615, 043016, 43016, 043024, 43024, 043028, 43028, 043036, 43036, 043040, 43040, 043045, 43045, 043616, 43616, M44015D, M44025D, M44030D, M44035D, M44040D, M44045D, M44115D
4.0	New template (version 2) Update of date of validity as per # 218149
5.0	Edition as per ISO 13485 certificate No Q5 022239 0094 Rev. 02
6.0	<ul style="list-style-type: none">• CC OM-CHC-FR09-194:<ul style="list-style-type: none">- Creation of references for harmonization of root codes Softima with root codes Flexima.- Cutting size of Softima Roll'Up Maxi 16-75mm becomes 15-75mm.• Removal of ref. 43670, 43918, 43935, M44215D.
7.0	CC OM-CHC-FR09-194: Removal of old root codes Softima after launch of new root codes according to version 6.0 of the present document
8.0	CC OM-CHC-FR09-292 : Deletion of references 044615 and 044670 (Registration of Flexima Closed Belgium references with the correct root codes: 044115 and 044170).
9.0	Update of date of validity as per #313578

Title: Déclaration EU conformité MDR - Flexima-Softima 1P Initiator: Sylvie Massenat

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