

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®-Softima® & Flexima®-Softima® Uro Silk**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, 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®-Softima® & Flexima®-Softima® Uro Silk**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, 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
044015	Flexima®-Softima® closed pouches Midi Beige cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	4039239000000103Z7
044015X1	Sample Flexima®-Softima® closed bag Midi Beige cut-to-fit 15-60 mm	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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
44225	Flexima®-Softima® closed pouches Mini Beige precut 25 mm by 30 units	Not Applicable	I	N	4039239000000103Z7
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
42716	Flexima®-Softima® drainable Roll'Up pouches Midi Split Cover cut-to-fit 15-60 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
42715	Flexima®-Softima® drainable Roll'Up pouches Midi Beige cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42715X1	Sample Flexima®-Softima® drainable Roll'Up bag Midi Beige cut-to-fit 15-60 mm	Not Applicable	I	N	4039239000000105ZB
42815	Flexima®-Softima® drainable Roll'Up pouches Midi Transparent cut-to-fit 15-60 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42725	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 25 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42730	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 30 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42735	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 35 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42740	Flexima®-Softima® drainable Roll'Up pouches Midi Beige precut 40 mm by 10, 30 units	Not Applicable	I	N	4039239000000105ZB
42776	Flexima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-76 mm by 30 units	Not Applicable	I	N	4039239000000105ZB
42776DE	Softima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-75 mm for Germany by 30 units	Not Applicable	I	N	4039239000000105ZB
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	4039239000000105ZB
42776K	Softima® drainable Roll'Up pouches Maxi Split Cover cut-to-fit 15-75 mm for Netherlands 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
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	40392390000019427
42718	Flexima®-Softima® drainable Roll'Up Convex pouches Midi Beige cut-to-fit 15-45 mm by 10 units	Not Applicable	I	N	40392390000019427

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
044913X1	Sample Flexima®-Softima® Uro Silk Urostomy bag Midi Transparent cut-to-fit 12-55 mm	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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
44830	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 30 mm by 30 units	Not Applicable	I	N	4039239000000107ZF
44836	Flexima® Uro Silk Urostomy pouches Midi Transparent precut 35 mm by 30 units	Not Applicable	I	N	4039239000000107ZF
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	4039239000000107ZF
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	4039239000000148934
44915	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent cut-to-fit 15-25 mm by 10 units	Not Applicable	I	N	4039239000000108ZH
44917	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	4039239000000108ZH
44919	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Beige cut-to-fit 15-35 mm by 10 units	Not Applicable	I	N	4039239000000108ZH
44920	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent precut 25 mm by 10 units	Not Applicable	I	N	4039239000000108ZH
44922	Flexima®-Softima® Uro Silk convex urostomy pouches Midi Transparent precut 30 mm by 10 units	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	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"><li>• CC OM-CHC-FR09-194:<ul style="list-style-type: none"><li>- Creation of references for harmonization of root codes Softima with root codes Flexima.</li><li>- Cutting size of Softima Roll'Up Maxi 16-75mm becomes 15-75mm.</li></ul></li><li>• Removal of ref. 43670, 43918, 43935, M44215D.</li></ul>
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
10.0	CC OM-CHC-FR09-314 : Creation of sample box reference (044015X1, 42715X1, 044913X1)
11.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

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

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Lori, Andrea (lorianit)  
Title: RA Specialist  
Date: Monday, 09 February 2026, 09:21 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Arico, Riccardo (aricrifr)  
Title: Site Director BBraun Medical SAS  
Date: Monday, 09 February 2026, 13:34 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Da Silva, Emmanuel (dasiemfr)  
Title: Responsable Qualité  
Date: Thursday, 12 February 2026, 18:14 W. Europe Daylight Time  
Meaning: Approve Document  
=====