

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 : 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**  
2026-12-31

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® & Flexima®-Softima® Uro Silk**Intended 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**  
2026-12-31

Saint-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 /<br>Article number | Designation   | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>Sterile | Basic-UDI-DI       |
|-------------------------------|---|---|-------------------|---------------------|--------------------|
| 044015                        | Flexima®-Softima® closed<br>pouches Midi Beige cut-to-fit<br>15-60 mm by 10, 30 units                           | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044015X1                      | Sample Flexima®-Softima®<br>closed bag Midi Beige<br>cut-to-fit 15-60 mm  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044025                        | Flexima®-Softima® closed<br>pouches Midi Beige precut 25<br>mm by 10, 30 units                                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044030                        | Flexima®-Softima® closed<br>pouches Midi Beige precut 30<br>mm by 10, 30 units                                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044035                        | Flexima®-Softima® closed<br>pouches Midi Beige precut 35<br>mm by 10, 30 units                                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044040                        | Flexima®-Softima® closed<br>pouches Midi Beige precut 40<br>mm by 10, 30 units                                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044045                        | Flexima®-Softima® closed<br>pouches Midi Beige precut 45<br>mm by 10, 30 units                                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044070                        | Flexima®-Softima® closed<br>pouches Maxi Beige with<br>inspection window cut-to-fit<br>15-75 mm by 10, 30 units | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044115                        | Flexima®-Softima® closed<br>pouches Midi Transparent<br>cut-to-fit 15-60 mm by 10, 30<br>units                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 044170                        | Flexima®-Softima® closed<br>pouches Maxi Transparent<br>cut-to-fit 15-75 mm by 10, 30<br>units                  | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 44212                         | Flexima®-Softima® closed<br>pouches Mini Beige cut-to-fit<br>15-45 mm by 30 units                               | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 44220                         | Flexima®-Softima® closed<br>pouches Mini Beige precut 20<br>mm by 30 units                                      | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |

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|-------------------------------|--|---|-------------------|---------------------|--------------------|
| 44225                         | Flexima®-Softima® closed<br>pouches Mini Beige precut 25<br>mm by 30 units                                       | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 44230                         | Flexima®-Softima® closed<br>pouches Mini Beige precut 30<br>mm by 30 units                                       | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| 44235                         | Flexima®-Softima® closed<br>pouches Mini Beige precut 35<br>mm by 30 units                                       | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44015D                       | Flexima® closed pouches Midi<br>Beige cut-to-fit 15-60 mm<br>with micropore rings for Spain<br>by 30 units       | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44025D                       | Flexima® closed pouches Midi<br>Beige precut 25 mm with<br>micropore rings for Spain by<br>30 units              | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44030D                       | Flexima® closed pouches Midi<br>Beige precut 30 mm with<br>micropore rings for Spain by<br>30 units              | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44035D                       | Flexima® closed pouches Midi<br>Beige precut 35 mm with<br>micropore rings for Spain by<br>30 units              | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44040D                       | Flexima® closed pouches Midi<br>Beige precut 40 mm with<br>micropore rings for Spain by<br>30 units              | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44045D                       | Flexima® closed pouches Midi<br>Beige precut 45 mm with<br>micropore rings for Spain by<br>30 units              | Not Applicable                          | I                 | N                   | 4039239000000103Z7 |
| M44070D                       | Flexima® closed pouches Maxi<br>Beige cut-to-fit 15-75 mm<br>with micropore rings for Spain<br>by 30 units       | Not Applicable                          | I                 | N                   | 40392390000014872Y |
| M44115D                       | Flexima® closed pouches Midi<br>Transparent cut-to-fit 15-60<br>mm with micropore rings for<br>Spain by 30 units | Not Applicable                          | I                 | N                   | 40392390000014872Y |

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

| Référence /<br>Article number | Designation  | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>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 |
| 42715X1                       | Sample Flexima®-Softima® drainable Roll'Up bag Midi Beige cut-to-fit 15-60 mm                          | 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 |

| Référence /<br>Article number | Designation   | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>Sterile | Basic-UDI-DI       |
|-------------------------------|---|---|-------------------|---------------------|--------------------|
| 42776K                        | Softima® drainable Roll'Up<br>pouches Maxi Split Cover cut-<br>to-fit 15-75 mm for<br>Netherlands by 30 units                   | Not Applicable                          | I                 | N                   | 403923900000105ZB  |
| 42876                         | Flexima® drainable Roll'Up<br>pouches Maxi Transparent<br>cut-to-fit 15-76 mm by 30<br>units                                    | Not Applicable                          | I                 | N                   | 403923900000105ZB  |
| 42876E                        | Softima® drainable Roll'Up<br>pouches Maxi Transparent<br>cut-to-fit 15-75 mm for<br>Ireland and UK by 30 units                 | Not Applicable                          | I                 | N                   | 403923900000105ZB  |
| 42715D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Beige cut-to-fit<br>15-60 mm + Micropore rings<br>for Spain by 30 units          | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42815D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Transparent<br>cut-to-fit 15-60 mm +<br>Micropore rings for Spain by<br>30 units | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42725D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Beige precut 25<br>mm + Micropore rings for<br>Spain by 30 units                 | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42730D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Beige precut 30<br>mm + Micropore rings for<br>Spain by 30 units                 | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42735D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Beige precut 35<br>mm + Micropore rings for<br>Spain by 30 units                 | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42740D                        | Set Flexima® drainable Roll'Up<br>pouches Midi Beige precut 40<br>mm + Micropore rings for<br>Spain by 30 units                 | Not Applicable                          | I                 | N                   | 403923900000148832 |
| 42717                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Beige cut-to-fit 15-35 mm by<br>10 units                          | Not Applicable                          | I                 | N                   | 40392390000019427  |

| Référence /<br>Article number | Designation   | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>Sterile | Basic-UDI-DI       |
|-------------------------------|---|---|-------------------|---------------------|--------------------|
| 42718                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Beige cut-to-fit 15-45 mm by<br>10 units          | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42719                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Split Cover cut-to-fit 15-35<br>mm by 10 units    | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42720                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Split Cover cut-to-fit 15-45<br>mm by 10 units    | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42726                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Beige precut 25 mm by 10<br>units                 | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42731                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Beige precut 30 mm by 10<br>units                 | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42817                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Transparent cut-to-fit 15-35<br>mm by 10 units    | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 42818                         | Flexima®-Softima® drainable<br>Roll'Up Convex pouches Midi<br>Transparent cut-to-fit 15-45<br>mm by 10 units    | Not Applicable                          | I                 | N                   | 403923900000019427 |
| 044913                        | Flexima®-Softima® Uro Silk<br>Urostomy pouches Midi<br>Transparent cut-to-fit 12-55<br>mm by 10, 20 or 30 units | Not Applicable                          | I                 | N                   | 4039239000000107ZF |
| 044913X1                      | Sample Flexima®-Softima®<br>Uro Silk Urostomy bag<br>Midi Transparent cut-to-fit<br>12-55 mm                    | Not Applicable                          | I                 | N                   | 4039239000000107ZF |
| 044914                        | Flexima®-Softima® Uro Silk<br>Urostomy pouches Midi Beige<br>cut-to-fit 12-55 mm by 10, 20<br>or 30 units       | Not Applicable                          | I                 | N                   | 4039239000000107ZF |

| Référence /<br>Article number | Designation  | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>Sterile | Basic-UDI-DI       |
|-------------------------------|--|---|-------------------|---------------------|--------------------|
| 44820                         | Flexima® Uro Silk Urostomy<br>pouches Midi Transparent<br>precut 20 mm by 30 units   | Not Applicable                          | I                 | N                   | 403923900000107ZF  |
| 44825                         | Flexima® Uro Silk Urostomy<br>pouches Midi Transparent<br>precut 25 mm by 30 units   | Not Applicable                          | I                 | N                   | 403923900000107ZF  |
| 44830                         | Flexima® Uro Silk Urostomy<br>pouches Midi Transparent<br>precut 30 mm by 30 units   | Not Applicable                          | I                 | N                   | 403923900000107ZF  |
| 44836                         | Flexima® Uro Silk Urostomy<br>pouches Midi Transparent<br>precut 35 mm by 30 units   | Not Applicable                          | I                 | N                   | 403923900000107ZF  |
| 044913AA                      | Flexima® Uro Silk Urostomy<br>pouches Midi Transparent<br>cut-to-fit 12-55 mm with 5<br>Connector Uro for Argentina<br>by 10+5 units (10 pouches + 5<br>connector) | Not Applicable                          | I                 | N                   | 403923900000107ZF  |
| 044913D                       | Set Flexima® Uro Silk<br>Urostomy pouches Midi<br>Transparent cut-to-fit 12-55<br>mm + 30 Micropores Rings for<br>Spain by 30 units                                | Not Applicable                          | I                 | N                   | 403923900000148934 |
| 44915                         | Flexima®-Softima® Uro Silk<br>convex urostomy pouches<br>Midi Transparent cut-to-fit<br>15-25 mm by 10 units   | Not Applicable                          | I                 | N                   | 403923900000108ZH  |
| 44917                         | Flexima®-Softima® Uro Silk<br>convex urostomy pouches<br>Midi Transparent cut-to-fit<br>15-35 mm by 10 units   | Not Applicable                          | I                 | N                   | 403923900000108ZH  |
| 44919                         | Flexima®-Softima® Uro Silk<br>convex urostomy pouches<br>Midi Beige cut-to-fit 15-35<br>mm by 10 units   | Not Applicable                          | I                 | N                   | 403923900000108ZH  |
| 44920                         | Flexima®-Softima® Uro Silk<br>convex urostomy pouches<br>Midi Transparent precut 25<br>mm by 10 units  | Not Applicable                          | I                 | N                   | 403923900000108ZH  |



| Référence /<br>Article number | Designation   | Certificat(s) CE /<br>EC Certificate(s) | Classe /<br>Class | Stérile/<br>Sterile | Basic-UDI-DI      |
|-------------------------------|---|---|-------------------|---------------------|-------------------|
| 44922                         | Flexima®-Softima® Uro Silk<br>convex urostomy pouches<br>Midi Transparent precut 30<br>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)<br>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)  |

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: Wednesday, 09 October 2024, 14:07 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

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Meaning: Approve Document  
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Title: Site Director - B.Braun Medical S.A.S (former CoE Stoma Care)  
Date: Thursday, 10 October 2024, 10:03 W. Europe Daylight Time  
Meaning: Approve Document  
=====