

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® 3SDestination : **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**
2012-09**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® 3SIntended 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**
2012-09**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
936415	Flexima®-Softima® Standard Base Plate diameter 45 mm cut-to-fit 15-30 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936420	Flexima®-Softima® Standard Base Plate diameter 45 mm precut 20 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936425	Flexima®-Softima® Standard Base Plate diameter 45 mm precut 25 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936430	Flexima®-Softima® Standard Base Plate diameter 45 mm precut 30 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936515	Flexima®-Softima® Standard Base Plate diameter 55 mm cut-to-fit 15-40 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936535	Flexima®-Softima® Standard Base Plate diameter 55 mm precut 35 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936540	Flexima®-Softima® Standard Base Plate diameter 55 mm precut 40 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936615	Flexima®-Softima® Standard Base Plate diameter 65 cut-to-fit 15-50 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936615X1	Sample Flexima®-Softima® Standard Base Plate diameter 65 cut-to-fit 15-50 mm	3S Not Applicable	I	N	4039239000000116ZG
936815	Flexima®-Softima® Standard Base Plate diameter 80 mm cut-to-fit 15-65 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG
936645	Flexima®-Softima® Standard Base Plate diameter 65 mm precut 45 mm by 5 or 10 units	3S Not Applicable	I	N	4039239000000116ZG

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
936415D	Flexima® 3S Set Standard Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 5 units	Not Applicable	I	N	4039239000000125ZH
936515D	Flexima 3S Set Standard Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 5 units	Not Applicable	I	N	4039239000000125ZH
936615D	Flexima® 3S Set Standard Base Plate diameter 65 cut-to-fit 15-50 mm + adhesive rings for Spain by 5 units	Not Applicable	I	N	4039239000000125ZH
936815D	Flexima®3S Set Standard Base Plate diameter 80 mm cut-to-fit 15-65 mm + adhesive rings for Spain by 5 units	Not Applicable	I	N	4039239000000125ZH
937415	Flexima®-Softima® 3S Base Plate Convex diameter 45 mm cut-to-fit 15-26mm by 5 units	Not Applicable	I	N	4039239000000117ZJ
937425	Flexima®-Softima® 3S Base Plate Convex diameter 45 mm precut 25 mm by 5 units	Not Applicable	I	N	4039239000000117ZJ
937515	Flexima®-Softima® 3S Base Plate Convex diameter 55 mm cut-to-fit 15-36 mm by 5 units	Not Applicable	I	N	4039239000000117ZJ
937530	Flexima®-Softima® 3S Base Plate Convex diameter 55 mm precut 30 mm by 5 units	Not Applicable	I	N	4039239000000117ZJ
937615	Flexima®-Softima® 3S Base Plate Convex diameter 65 mm cut-to-fit 15-46 mm by 5 units	Not Applicable	I	N	4039239000000117ZJ
942445D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige Et Base Plate Convex diameter 45 mm cut-to-fit 15-26mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000129ZR
942455D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige Et Base Plate Convex diameter 55 mm cut-to-fit 15-36 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000129ZR

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
942465D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige & Base Plate Convex diameter 65 mm cut-to-fit 15-46 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000129ZR
942425D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige & Base Plate Convex diameter 45 mm precut 25 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000129ZR
931045	Flexima®-Softima® 3S Closed pouch Midi Beige diameter 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931055	Flexima®-Softima® 3S Closed pouch Midi Beige diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931065	Flexima®-Softima® 3S Closed pouch Midi Beige diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931065X1	Sample Flexima®-Softima® 3S Closed bag Midi Beige diameter 65 mm	Not Applicable	I	N	4039239000000121ZR
931445	Flexima®-Softima® 3S Closed pouch Maxi Beige diameter 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931455	Flexima®-Softima® 3S Closed pouch Maxi Beige diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931465	Flexima®-Softima® 3S Closed pouch Maxi Beige diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931480	Flexima®-Softima® 3S Closed pouch Maxi Beige diameter 80 mm by 10 or 30 units	Not Applicable	I	N	4039239000000121ZR
931545	Flexima®-Softima® 3S Closed pouch Maxi Transparent diameter 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931555	Flexima®-Softima® 3S Closed pouch Maxi Transparent diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR
931565	Flexima®-Softima® 3S Closed pouch Maxi Transparent diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000121ZR

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
931580	Flexima®-Softima® 3S Closed pouch Maxi Transparent diameter 80 mm by 10 or 30 units	Not Applicable	I	N	4039239000000121Z9
931445D	Flexima® 3S Set Closed pouch Maxi Beige Et Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931455D	Flexima® 3S Set Closed pouch Maxi Beige Et Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931465D	Flexima® 3S Set Closed pouch Maxi Beige Et Base Plate diameter 65 mm cut-to-fit 15-50 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931480D	Flexima® 3S Set Closed pouch Maxi Beige Et Base Plate diameter 80 mm cut-to-fit 15-65 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931545D	Flexima® 3S Set Closed pouch Maxi Transparent Et Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931555D	Flexima® 3S Set Closed pouch Maxi Transparent Et Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931565D	Flexima® 3S Set Closed pouch Maxi Transparent Et Base Plate diameter 65 mm cut-to-fit 15-50 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK
931580D	Flexima® 3S Set Closed pouch Maxi Transparent Et Base Plate diameter 80 mm cut-to-fit 15-65 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000126ZK

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
941430D	Flexima® 3S Set Closed pouch Maxi Beige Et Convex Base Plate diameter 55 mm precut 30 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000127ZM
941445D	Flexima® 3S Set Closed pouch Maxi Beige Et Convex Base Plate diameter 45 mm cut-to- fit 15-26 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000127ZM
941455D	Flexima® 3S Set Closed pouch Maxi Beige Et Convex Base Plate diameter 55 mm cut-to- fit 15-36 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000127ZM
941465D	Flexima® 3S Set Closed pouch Maxi Beige Et Convex Base Plate diameter 65 mm cut-to- fit 15-46 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000127ZM
932045	Flexima®-Softima® 3S drainable Roll'Up Midi Beige diameter 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB
932055	Flexima®-Softima® 3S drainable Roll'Up Midi Beige diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB
932065	Flexima®-Softima® 3S drainable Roll'Up Midi Beige diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB
932065X1	Sample Flexima®-Softima® 3S drainable Roll'Up bag Midi Beige diameter 65 mm	Not Applicable	I	N	4039239000000122ZB
932145	Flexima®-Softima® 3S drainable Roll'Up Midi Transparent diameter 45 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB
932155	Flexima®-Softima® 3S drainable Roll'Up Midi Transparent diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB
932165	Flexima®-Softima® 3S drainable Roll'Up Midi Transparent diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000122ZB

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
932445	Flexima®-Softima® drainable Roll'Up Maxi Beige diameter 45 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932455	Flexima®-Softima® drainable Roll'Up Maxi Beige diameter 55 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932465	Flexima®-Softima® drainable Roll'Up Maxi Beige diameter 65 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932480	Flexima®-Softima® drainable Roll'Up Maxi Beige diameter 80 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000122ZB
932545	Flexima®-Softima® drainable Roll'Up Maxi Transparent diameter 45 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932555	Flexima®-Softima® drainable Roll'Up Maxi Transparent diameter 55 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932565	Flexima®-Softima® drainable Roll'Up Maxi Transparent diameter 65 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000122ZB
932580	Flexima®-Softima® drainable Roll'Up Maxi Transparent diameter 80 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000122ZB
932445D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige & Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 30-10 units	3S Not Applicable	I	N	4039239000000128ZP
932455D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige & Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 30-10 units	3S Not Applicable	I	N	4039239000000128ZP

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
932465D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Beige & Base Plate diameter 65 mm cut-to-fit 15-50 mm + adhesive rings for Spain by 30-10 units	Not Applicable	I	N	4039239000000128ZP
932545D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Transparent & Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 30-10 units	Not Applicable	I	N	4039239000000128ZP
932555D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Transparent & Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 30-10 units	Not Applicable	I	N	4039239000000128ZP
932565D	Flexima® 3S Set Drainable Roll'Up pouch Maxi Transparent & Base Plate diameter 65 mm cut-to-fit 15-50 mm + adhesive rings for Spain by 30-10 units	Not Applicable	I	N	4039239000000128ZP
933055	Flexima®-Softima® 3S drainable High Flow Beige with inspection window diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000123ZD
933065	Flexima®-Softima® 3S drainable High Flow Beige with inspection window diameter 65 mm by 10, 30 units	Not Applicable	I	N	4039239000000123ZD
933065X1	Sample Flexima®-Softima® 3S drainable High Flow bag Split Cover diameter 65 mm	Not Applicable	I	N	4039239000000123ZD
933080	Flexima®-Softima® 3S drainable High Flow Beige with inspection window diameter 80 mm by 10 or 30 units	Not Applicable	I	N	4039239000000123ZD
933155	Flexima®-Softima® 3S drainable High Flow Transparent diameter 55 mm by 10, 30 units	Not Applicable	I	N	4039239000000123ZD

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
933165	Flexima®-Softima® drainable High Flow Transparent diameter 65 mm by 10, 30 units	3S Not Applicable	I	N	4039239000000123ZD
933180	Flexima®-Softima® drainable High Flow Transparent diameter 80 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000123ZD
934045	Flexima®-Softima® urostomy Midi Beige with inspection window diameter 45 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934055	Flexima®-Softima® urostomy Midi Beige with inspection window diameter 55 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934065	Flexima®-Softima® urostomy Midi Beige with inspection window diameter 65 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934145	Flexima®-Softima® urostomy Midi Transparent diameter 45 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934155	Flexima®-Softima® urostomy Midi Transparent diameter 55 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934165	Flexima®-Softima® urostomy Midi Transparent diameter 65 mm by 10 or 30 units	3S Not Applicable	I	N	4039239000000124ZF
934145D	Flexima® 3S Set Urostomy pouch Midi Transparent & Base Plate diameter 45 mm cut-to-fit 15-30 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000130ZA
934155D	Flexima® 3S Set Urostomy pouch Midi Transparent & Base Plate diameter 55 mm cut-to-fit 15-40 mm + adhesive rings for Spain by 30+7 units	Not Applicable	I	N	4039239000000130ZA

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
944045D	Flexima® 3S Set Urostomy pouch Midi Transparent & Convex Base Plate diameter 45 mm cut-to-fit 15-26 mm for Spain by 30+7 units	Not Applicable	I	N	403923900000131ZC
944055D	Flexima® 3S Set Urostomy pouch Midi Transparent & Convex Base Plate diameter 55 mm cut-to-fit 15-36 mm for Spain by 30+7 units	Not Applicable	I	N	403923900000131ZC
944225D	Flexima® 3S Set Urostomy pouch Midi Transparent & Convex Base Plate diameter 45 mm precut 25 mm for Spain by 30+7 units	Not Applicable	I	N	403923900000131ZC

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	CC OM-CHC-FR09-161 - Creation of reference Flexima/Softima 3S Ø 80.
5.0	Update of date of validity as per #313578
6.0	CC OM-CHC-FR09-314 : Creation of sample box reference (936615X1, 931065X1, 932065X1, 933065X1)
7.0	CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use.

Title: Déclaration EU conformité MDR - Flexima-Softima 3S 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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