

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® KeyDestination : Système de recueil 2-pièces Supports standards
et convexes, Poches fermées, vidables Roll'Up et Maxi 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**

2005-01

Valable jusqu'au

2023-12-31

suivant notre Certificat ISO (*dispositifs de classe I*)hereby declare under our own responsibility that the
product/s

Basic-UDI-DI (see attachment I)

Flexima®-Softima® KeyIntended purpose: 2-piece collection system Base plates Standard
and convex, Closed, drainable Roll'Up and Maxi and urostomy

(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**

2005-01

Valid until

2023-12-31

according to our valid ISO Certificate (*class I devices*)

Saint-Jean-de-Luz, See Date of B.DoCS Signature

Saint-Cloud, See Date of B.DoCS Signature

Name/Position: Riccardo Arico
Site DirectorName / Position: Manuelle Schneider-Ponsot
Director of Regulatory and Pharmaceutical
Operation Safety Officer

See B.DoCS signature page

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
62040	Flexima®-Softima® Key Standard Base Plate diameter 40 mm cut-to-fit 15-35 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
62050	Flexima®-Softima® Key Standard Base Plate diameter 50 mm cut-to-fit 15-45 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
62060	Flexima®-Softima® Key Standard Base Plate diameter 60 mm cut-to-fit 15-55 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
62080	Flexima®-Softima® Key Standard Base Plate diameter 80 mm cut-to-fit 15-75 mm by 5 or 10-units	Not Applicable	I	N	4039239000000132ZE
63040	Softima® Key Standard Base Plate diameter 40 mm cut-to- fit 15-35 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
63050	Softima® Key Standard Base Plate diameter 50 mm cut-to- fit 15-45 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
63060	Softima® Key Standard Base Plate diameter 60 mm cut-to- fit 15-55 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
63080	Softima® Key Standard Base Plate diameter 80 mm cut-to- fit 15-75 mm by 5 or 10 units	Not Applicable	I	N	4039239000000132ZE
62052	Flexima®-Softima® Key Convex Base Plate diameter 50 mm cut-to-fit 15-25 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62062	Flexima®-Softima® Key Convex Base Plate diameter 60 mm cut-to-fit 15-35 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62063	Flexima®-Softima® Key Convex Base Plate diameter 60 mm cut-to-fit 15-45 mm by 5 units	Not Applicable	I	N	4039239000000133ZG

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
62064	Flexima®-Softima® Key Convex Base Plate diameter 60 mm precut 25 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62066	Flexima®-Softima® Key Convex Base Plate diameter 60 mm precut 30 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62067	Flexima®-Softima® Key Convex Base Plate diameter 60 mm precut 35 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62069	Flexima®-Softima® Key Convex Base Plate diameter 60 mm precut 40 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63052	Softima® Key Convex Base Plate diameter 50 mm cut-to- fit 15-25 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63062	Softima® Key Convex Base Plate diameter 60 mm cut-to- fit 15-35 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63063	Softima® Key Convex Base Plate diameter 60 mm cut-to- fit 15-45 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63064	Softima® Key Convex Base Plate diameter 60 mm precut 25 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63066	Softima® Key Convex Base Plate diameter 60 mm precut 30 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63067	Softima® Key Convex Base Plate diameter 60 mm precut 35 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
63069	Softima® Key Convex Base Plate diameter 60 mm precut 40 mm by 5 units	Not Applicable	I	N	4039239000000133ZG
62140	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62150	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000135ZL

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
62160	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 60 mm by 30 units	Not Applicable	I	N	403923900000135ZL
62180	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 80 mm by 30 units	Not Applicable	I	N	403923900000135ZL
62240	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 40 mm by 30 units	Not Applicable	I	N	403923900000135ZL
62250	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 50 mm by 30 units	Not Applicable	I	N	403923900000135ZL
62260	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 60 mm by 30 units	Not Applicable	I	N	403923900000135ZL
62280	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 80 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63140	Softima® Key Closed pouch Midi Beige Diameter 40 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63150	Softima® Key Closed pouch Midi Beige Diameter 50 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63160	Softima® Key Closed pouch Midi Beige Diameter 60 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63180	Softima® Key Closed pouch Midi Beige Diameter 80 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63240	Softima® Key Closed pouch Midi Transparent Diameter 40 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63250	Softima® Key Closed pouch Midi Transparent Diameter 50 mm by 30 units	Not Applicable	I	N	403923900000135ZL
63260	Softima® Key Closed pouch Midi Transparent Diameter 60 mm by 30 units	Not Applicable	I	N	403923900000135ZL

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
63280	Softima® Key Closed pouch Midi Transparent Diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62550	Flexima®-Softima® Key drainable Maxi pouch Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
62650	Flexima® Key drainable Maxi pouch Transparent diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
62560	Flexima®-Softima® Key drainable Maxi pouch Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
62660	Flexima® Key drainable Maxi pouch Transparent diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
62680	Flexima®-Softima® Key drainable Maxi pouch Transparent diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
63550	Softima® Key drainable Maxi pouch Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
63560	Softima® Key drainable Maxi pouch Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
63680	Softima® Key drainable Maxi pouch Transparent diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000137ZQ
621240	Flexima®-Softima® Key drainable Roll'Up pouch Midi Transparent diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621241	Flexima®-Softima® Key drainable Roll'Up pouch Midi Beige diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621250	Flexima®-Softima® Key drainable Roll'Up pouch Midi Transparent diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000136ZN

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
621251	Flexima®-Softima® Key drainable Roll'Up pouch Midi Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621260	Flexima®-Softima® Key drainable Roll'Up pouch Maxi Transparent diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621261	Flexima®-Softima® Key drainable Roll'Up pouch Maxi Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621280	Flexima®-Softima® Key drainable Roll'Up pouch Maxi Transparent diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621281	Flexima®-Softima® Key drainable Roll'Up pouch Maxi Beige diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631280	Softima® Key drainable Roll'Up pouch Maxi Transparent diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631240	Softima® Key drainable Roll'Up pouch Midi Transparent diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631241	Softima® Key drainable Roll'Up pouch Midi Beige diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631250	Softima® Key drainable Roll'Up pouch Midi Transparent diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631251	Softima® Key drainable Roll'Up pouch Midi Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631260	Softima® Key drainable Roll'Up pouch Maxi Transparent diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000136ZN

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
631261	Softima® Key drainable Roll'Up pouch Maxi Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
631281	Softima® Key drainable Roll'Up pouch Maxi Beige diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
64140D	Flexima® Key Set Closed pouch Midi Beige & Standard Base Plate diameter 40 mm cut-to-fit 15-35 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64150D	Flexima® Key Set Closed pouch Midi Beige & Standard Base Plate diameter 50 mm cut-to-fit 15-45 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64160D	Flexima® Key Set Closed pouch Midi Beige & Standard Base Plate diameter 60 mm cut-to-fit 15-55 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64180D	Flexima® Key Set Closed pouch Midi Beige & Standard Base Plate diameter 80 mm cut-to-fit 15-75 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64240D	Flexima® Key Set Closed pouch Midi Transparent & Standard Base Plate diameter 40 mm cut-to-fit 15-35 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64250D	Flexima® Key Set Closed pouch Midi Transparent & Standard Base Plate diameter 50 cut-to-fit 15-45 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU
64260D	Flexima® Key Set Closed pouch Midi Transparent & Standard Base Plate diameter 60 mm cut-to-fit 15-55 mm for Spain by 30+7 units	Not Applicable	I	N	4039239000000139ZU

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
64280D	Flexima® Key Set Closed pouch Midi Transparent & Standard Base Plate diameter 80 mm cut-to-fit 15-75 mm for Spain by 30+7 units	Not Applicable	I	N	403923900000139ZU
65150D	Flexima® Key Set Closed pouch Midi Beige & Convex Base Plate diameter 50 mm cut-to-fit 15-25 mm for Spain by 30 + 7 units and 7 Micropore Rings	Not Applicable	I	N	40392390000027252Y
65160D	Flexima® Key Set Closed pouch Midi Beige & Convex Base Plate diameter 60 mm cut-to-fit 15-45 mm for Spain by 30 + 7 units and 7 Micropore Rings	Not Applicable	I	N	40392390000027252Y
641240D	Flexima® Key Set drainable Roll'Up pouch Midi Transparent & Standard Base Plate diameter 40 mm cut-to- fit 15-35 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD
641241D	Flexima® Key Set drainable Roll'Up pouch Midi Beige & Standard Base Plate diameter 40 mm cut-to-fit 15-35 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD
641250D	Flexima® Key Set drainable Roll'Up pouch Midi Transparent & Standard Base Plate diameter 50 mm cut-to- fit 15-45 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD
641251D	Flexima® Key Set drainable Roll'Up pouch Midi Beige & Standard Base Plate diameter 50 mm cut-to-fit 15-45 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD
641260D	Flexima® Key Set drainable Roll'Up pouch Maxi Transparent & Standard Base Plate diameter 60 mm cut-to- fit 15-55 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
641261D	Flexima® Key Set drainable Roll'Up pouch Maxi Beige Et Standard Base Plate diameter 60 mm cut-to-fit 15-55 mm for Spain by 30+10 units	Not Applicable	I	N	4039239000000140ZD
651251D	Flexima® Key Set Roll'up pouch Midi Beige Et Convex Base Plate diameter 50 mm cut-to-fit 15-25 mm for Spain by 30 + 10 units and 10 Micropores Rings	Not Applicable	I	N	403923900000272632
651261D	Flexima® Key Set Closed pouch Midi Beige Et Convex Base Plate diameter 60 mm cut-to-fit 15-45 mm for Spain by 30 + 10 units and 10 Micropore Rings	Not Applicable	I	N	403923900000272632
62740	Flexima®-Softima® Key Urostomy pouch Midi Beige diameter 40 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
62750	Flexima®-Softima® Key Urostomy pouch Midi Beige diameter 50 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
62760	Flexima®-Softima® Key Urostomy pouch Midi Beige diameter 60 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
62840	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 40 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
62850	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 50 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
62860	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 60 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS
63740	Softima® Key Urostomy pouch Midi Beige diameter 40 mm by 20 units	Not Applicable	I	N	4039239000000138ZS

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
63750	Softima® Key Urostomy pouch Midi Beige diameter 50 mm by 20 units	Not Applicable	I	N	403923900000138ZS
63760	Softima® Key Urostomy pouch Midi Beige diameter 60 mm by 20 units	Not Applicable	I	N	403923900000138ZS
63840	Softima® Key Urostomy pouch Midi Transparent diameter 40 mm by 20 units	Not Applicable	I	N	403923900000138ZS
63850	Softima® Key Urostomy pouch Midi Transparent diameter 50 mm by 20 units	Not Applicable	I	N	403923900000138ZS
63860	Softima® Key Urostomy pouch Midi Transparent diameter 60 mm by 20 units	Not Applicable	I	N	403923900000138ZS
65850D	Flexima® Key Set Uro pouch Transparent & Flat Base Plate diameter 50 mm cut-to-fit 15-45 mm for Spain by 30 + 7 units and 7 Micropore Rings	Not Applicable	I	N	403923900000272734
65860D	Flexima® Key Set Uro pouch Transparent & Flat Base Plate diameter 60 mm cut-to-fit 15-55 mm for Spain by 30 + 7 units and 7 Micropore Rings	Not Applicable	I	N	403923900000272734

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 Closed pouches diameter 40mm and 50mm: 62140, 63140, 62240, 63240, 62150, 63150, 62250, 63250, 64140D, 64240D, 64150D and 64250D.
3.0	New template (version 2) Update of date of validity as per # 218149.
4.0	Edition as per ISO 13485 certificate No Q5 022239 0094 Rev. 02
5.0	Flexima/Softima Key Uro packaging update as per # 226717 (packaging by 20 units).
6.0	CC OM-CHC-FR09-194: Creation of references for harmonization of root codes Softima with root codes Flexima.
7.0	CC OM-CHC-FR09-203: Creation of references for Key Sets Spain.

Title: Déclaration EU conformité MDR - Flexima-Softima Key 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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Effective