Nous | We

B. BRAUN MEDICAL SAS
SRN FR-MF-000000674
26 Rue Armengaud
92210 Saint-Cloud
FRANCE

déclarons par les présentes et sous notre seule responsabilité que le/les produit/s

Basic-UDI-DI (voir annexe I)

Flexima®-Softima® Key
Destination : Système de recueil 2-pièces Supports standards, convexe et soft convexe, 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, 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
2005-01

Valable jusqu'au
2026-12-31

hereby declare under our own responsibility that the product/s

Basic-UDI-DI (see attachment I)

Flexima®-Softima® Key,
Intended purpose: 2-piece collection system Base plates Standard, convex and soft convex, Closed, Drainable Roll'Up and Maxi and Urostomy pouches

(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
2005-01

Valid until
2026-12-31

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

Name/Position: Riccardo Arico
Site Director

See B.DoCS signature page

Saint-Cloud, *See Date of B.DoCS Signature*

Name / Position: Emmanuel Da Silva
Quality Manager - PRRC

See B.DoCS signature page

Effective

BBMF-M-5-2-01-004-2_2.0

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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
62050X1	Sample Flexima®-Softima® Key Standard Base Plate diameter 50 mm cut-to-fit 15-45 mm	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
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
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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
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
62362	Flexima®-Softima® Key 2-piece system, Soft convex base plate, cut-to-fit Ø60 mm /15-35mm	Not Applicable	I	N	4039239000000133ZG
62363	Flexima®-Softima® Key 2-piece system, Soft convex base plate, pre-cut Ø60/25 mm	Not Applicable	I	N	4039239000000133ZG
62364	Flexima®-Softima® Key 2-piece system, Soft convex base plate, pre-cut Ø60/30 mm	Not Applicable	I	N	4039239000000133ZG
62160	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62180	Flexima®-Softima® Key Closed pouch Midi Beige Diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62240	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62250	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62260	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000135ZL
62280	Flexima®-Softima® Key Closed pouch Midi Transparent Diameter 80 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
62550	Flexima®-Softima® Key drainable Maxi pouch Beige diameter 50 mm by 30 units	Not Applicable	I	N	403923900000137ZQ
62650	Flexima® Key drainable Maxi pouch Transparent diameter 50 mm by 30 units	Not Applicable	I	N	403923900000137ZQ
62560	Flexima®-Softima® Key drainable Maxi pouch Beige diameter 60 mm by 30 units	Not Applicable	I	N	403923900000137ZQ
62660	Flexima® Key drainable Maxi pouch Transparent diameter 60 mm by 30 units	Not Applicable	I	N	403923900000137ZQ
62680	Flexima®-Softima® Key drainable Maxi pouch Transparent diameter 80 mm by 30 units	Not Applicable	I	N	403923900000137ZQ
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
621251	Flexima®-Softima® Key drainable Roll'Up pouch Midi Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000136ZN
621251X1	Sample Flexima®-Softima® Key drainable Roll'Up bag Midi Beige diameter 50 mm	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

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
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
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	4039239000000139ZU
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 & 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 & 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 & 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	40392390000000138ZS
62750	Flexima®-Softima® Key Urostomy pouch Midi Beige diameter 50 mm by 20 or 30 units	Not Applicable	I	N	40392390000000138ZS
62760	Flexima®-Softima® Key Urostomy pouch Midi Beige diameter 60 mm by 20 or 30 units	Not Applicable	I	N	40392390000000138ZS
62840	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 40 mm by 20 or 30 units	Not Applicable	I	N	40392390000000138ZS
62850	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 50 mm by 20 or 30 units	Not Applicable	I	N	40392390000000138ZS
62860	Flexima®-Softima® Key Urostomy pouch Midi Transparent diameter 60 mm by 20 or 30 units	Not Applicable	I	N	4039239000000138ZS

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.
8.0	CC OM-CHC-FR09-203: Cancellation of the Flexima Key Uro Set Spain Ref. 65850D and 65860D (not approved by Spain Ministry)
9.0	CC FR09-194: Removal of old root codes Softima after launch of new root codes according to version 6.0 of the present document
10.0	Update of date of validity as per #313578
11.0	CC OM-CHC-FR09-314 : Creation of sample box reference (62050X1, 62150X1, 621251X1)
12.0	CC OM-CHC-FR09-402: Creation of Soft Convex Base Plates (62362, 62363 and 62364)

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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