

Nous

We

B. BRAUN MEDICAL SAS**SRN FR-MF-00000674**

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® Key

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, 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

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® Key

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, 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-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 |
|-------------------------------|--|---|-------------------|---------------------|--------------------|
| 62040L | Flexima® Key Standard Base Plate diameter 40 mm cut-to- fit 15-35 mm | Not Applicable | I | N | 4039239000000132ZE |
| 62050L | Flexima® Key Standard Base Plate diameter 50 mm cut-to- fit 15-45 mm | Not Applicable | I | N | 4039239000000132ZE |
| 62060L | Flexima® Key Standard Base Plate diameter 60 mm cut-to- fit 15-55 mm | Not Applicable | I | N | 4039239000000132ZE |
| 62080L | Flexima® Key Standard Base Plate diameter 80 mm cut-to- fit 15-75 mm | Not Applicable | I | N | 4039239000000132ZE |
| 62052L | Flexima® Key Convex Base Plate diameter 50 mm cut-to- fit 15-25 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62062L | Flexima® Key Convex Base Plate diameter 60 mm cut-to- fit 15-35 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62063L | Flexima® Key Convex Base Plate diameter 60 mm cut-to- fit 15-45 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62064L | Flexima® Key Convex Base Plate diameter 60 mm precut 25 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62066L | Flexima® Key Convex Base Plate diameter 60 mm precut 30 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62067L | Flexima® Key Convex Base Plate diameter 60 mm precut 35 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62069L | Flexima® Key Convex Base Plate diameter 60 mm precut 40 mm | Not Applicable | I | N | 4039239000000133ZG |
| 62362L | Flexima® Key Soft convex Base Plate diameter 60 cut- to-fit 15-35mm | Not Applicable | I | N | 4039239000000133ZG |
| 62140L | Flexima® Key Closed pouch Midi Beige Diameter 40 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62150L | Flexima® Key Closed pouch Midi Beige Diameter 50 mm | Not Applicable | I | N | 4039239000000135ZL |

| Référence / Article number | Designation | Certificat(s) CE / EC Certificate(s) | Classe / Class | Stérile/ Sterile | Basic-UDI-DI |
|-------------------------------|--|---|-------------------|---------------------|--------------------|
| 62160L | Flexima® Key Closed pouch Midi Beige Diameter 60 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62180L | Flexima® Key Closed pouch Midi Beige Diameter 80 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62240L | Flexima® Key Closed pouch Midi Transparent Diameter 40 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62250L | Flexima® Key Closed pouch Midi Transparent Diameter 50 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62260L | Flexima® Key Closed pouch Midi Transparent Diameter 60 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62280L | Flexima® Key Closed pouch Midi Transparent Diameter 80 mm | Not Applicable | I | N | 4039239000000135ZL |
| 62550L | Flexima® Key drainable Maxi pouch Beige diameter 50 mm | Not Applicable | I | N | 4039239000000137ZQ |
| 621240L | Flexima® Key drainable Roll'Up pouch Midi Transparent diameter 40 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621241L | Flexima® Key drainable Roll'Up pouch Midi Beige diameter 40 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621250L | Flexima® Key drainable Roll'Up pouch Midi Transparent diameter 50 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621251L | Flexima® Key drainable Roll'Up pouch Midi Beige diameter 50 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621260L | Flexima® Key drainable Roll'Up pouch Maxi Transparent diameter 60 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621261L | Flexima® Key drainable Roll'Up pouch Maxi Beige diameter 60 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621280L | Flexima® Key drainable Roll'Up pouch Maxi Transparent diameter 80 mm | Not Applicable | I | N | 4039239000000136ZN |
| 621281L | Flexima® Key drainable Roll'Up pouch Maxi Beige diameter 80 mm | Not Applicable | I | N | 4039239000000136ZN |

| Référence / Article number | Designation | Certificat(s) CE / EC Certificate(s) | Classe / Class | Stérile/ Sterile | Basic-UDI-DI |
|-------------------------------|---|---|-------------------|---------------------|-------------------|
| 62740L | Flexima® Key Urostomy pouch Midi Beige diameter 40 mm | Not Applicable | I | N | 403923900000138ZS |
| 62750L | Flexima® Key Urostomy pouch Midi Beige diameter 50 mm | Not Applicable | I | N | 403923900000138ZS |
| 62760L | Flexima® Key Urostomy pouch Midi Beige diameter 60 mm | Not Applicable | I | N | 403923900000138ZS |
| 62840L | Flexima® Key Urostomy pouch Midi Transparent diameter 40 mm | Not Applicable | I | N | 403923900000138ZS |
| 62850L | Flexima® Key Urostomy pouch Midi Transparent diameter 50 mm | Not Applicable | I | N | 403923900000138ZS |
| 62860L | Flexima® Key Urostomy pouch Midi Transparent diameter 60 mm | Not Applicable | I | N | 403923900000138ZS |

Annexe II / Attachment II: Spécifications communes/ Common specifications

Not applicable

Effective

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

Document amendment information

| Version | Description of the changes |
|---------|---|
| 1.0 | Initial creation as per MDR |
| 2.0 | CC OM-CHC-FR09-402: Creation of Soft Convex Base Plate (62362L) |
| 3.0 | CC OM-CHC-FR09-256 : Update of the DoC for the Intended Use. |

Title: Flexima Key - Déclaration EU conformité MDR - Portugal 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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