

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)

Proxima® / Proxima®+ / Proxima® BorderDestination : Poches de recueil 1-pièce fermées et vidables
avec clamp

(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**
2006-01**Valable jusqu'au**
2023-12-31
suivant notre Certificat ISO (*dispositifs de classe I*)Saint-Jean-de-Luz, See Date of B.DoCS Signature
Name/Position: Laurent Buono
Site Director

See B.DoCS signature page

hereby declare under our own responsibility that the
product/s

Basic-UDI-DI (See attachment I)

Proxima® / Proxima®+ / Proxima® BorderIntended purpose: 1-piece collection pouches closed and
drainable with clamp

(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**
2006-01**Valid until**
2023-12-31
according to our valid ISO Certificate (*class I devices*)Saint-Cloud, See Date of B.DoCS Signature
Name / Position: Manuelle Schneider-Ponsot
Director of Regulatory and Pharmaceutical Operation
Safety Officer

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
55010	Proxima® closed pouch Beige cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000109ZK
55110	Proxima® closed pouch Transparent cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000109ZK
55410	Proxima® drainable pouch with clamp Beige cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000112Z8
55510	Proxima® drainable pouch with clamp Transparent cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000112Z8
54010	Proxima®+ closed pouch with filter Beige cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000110Z4
54110	Proxima®+ closed pouch with filter Transparent cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000110Z4
54410	Proxima®+ drainable pouch with filter Beige cut-to-fit 10-70 mm by 10 units	Not Applicable	I	N	4039239000000113ZA
54510	Proxima®+ drainable pouch with filter Transparent cut-to-fit 10-70 mm by 10 units	Not Applicable	I	N	4039239000000113ZA
56410	Proxima® Border drainable pouch with clamp Beige cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000111Z6
56510	Proxima® Border drainable pouch with clamp Transparent cut-to-fit 10-70 mm by 30 units	Not Applicable	I	N	4039239000000111Z6

Annexe II / Attachment II: Spécifications communes/ Common specifications

Not applicable

Effective

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

Title: Déclaration EU conformité MDR - Proxima 1p Initiator: Sylvie Massenat

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Desplat, Isabelle (despisfr)
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Date: Wednesday, 29 September 2021, 09:36 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Buono, Laurent (buonlafr)
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Meaning: Approve Document
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UserName: Schneider-Ponsot, Manuelle (schnmafr)
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Date: Monday, 04 October 2021, 09:28 W. Europe Daylight Time
Meaning: Approve Document
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