

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**
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)

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**
2026-12-31Saint-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

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	Update of date of validity as per #313578

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: Jeleazcova, Ecaterina (jeleecro)
Title: RO01 Jr. Manager GRA MD Avitum-Stoma Care
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Meaning: Document signed as Author
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UserName: Arico, Riccardo (aricride)
Title: Site Director - B.Braun Medical S.A.S (former CoE Stoma Care)
Date: Friday, 08 December 2023, 16:31 W. Europe Daylight Time
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UserName: Schneider Ponsot, Manuelle (schnmafr)
Title: Quality Director / Safety Officer / Resp Pharmacist
Date: Friday, 15 December 2023, 09:58 W. Europe Daylight Time
Meaning: Approve Document
=====

Effective