

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 2 / Proxima 2+Destination : Système de recueil 2-pièces Supports Standards,
Convexes et avec Tape Border, poches fermées, vidables avec
clamp 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**

2006-01

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)

Proxima 2 / Proxima 2+Intended purpose: 2-piece collection system Base Plates
Standard, Convex and with Tape Border, closed, drainable with
clamp and urostomy pouches

(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

2026-12-31

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
73040	Proxima® 2 Standard Base plate diameter 40 mm cut- to-fit 12-35 mm by 10 units	Not Applicable	I	N	4039239000000141ZF
73050	Proxima® 2 Standard Base plate diameter 50 mm cut- to-fit 12-45 mm by 10 units	Not Applicable	I	N	4039239000000141ZF
73060	Proxima® 2 Standard Base plate diameter 60 mm cut- to-fit 12-55 mm by 10 units	Not Applicable	I	N	4039239000000141ZF
73080	Proxima® 2 Standard Base plate diameter 80 mm cut- to-fit 12-75 mm by 10 units	Not Applicable	I	N	4039239000000141ZF
77050	Proxima® 2 Convex base plate diameter 50 mm cut- to-fit 15-30 mm by 5 units	Not Applicable	I	N	4039239000000142ZH
77060	Proxima® 2 Convex base plate diameter 60 mm cut- to-fit 15-40 mm by 5 units	Not Applicable	I	N	4039239000000142ZH
77080	Proxima® 2 Convex base plate diameter 80 mm cut- to-fit 15-60 mm by 5 units	Not Applicable	I	N	4039239000000142ZH
76040	Proxima® 2+ Base Plate with tape border diameter 40 cut- to-fit 12-35 mm by 10 units	Not Applicable	I	N	4039239000000143ZK
76050	Proxima® 2+ Base Plate with tape border diameter 50 cut- to-fit 12-45 mm by 10 units	Not Applicable	I	N	4039239000000143ZK
76060	Proxima® 2+ Base Plate with tape border diameter 60 cut- to-fit 12-55 mm by 10 units	Not Applicable	I	N	4039239000000143ZK
76080	Proxima® 2+ Base Plate with tape border diameter 80 cut- to-fit 12-75 mm by 10 units	Not Applicable	I	N	4039239000000143ZK
73140	Proxima® 2 closed pouch Beige diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000145ZP
73150	Proxima® 2 closed pouch Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000145ZP
73160	Proxima® 2 closed pouch Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000145ZP
73180	Proxima® 2 closed pouch Beige diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000145ZP

Effective

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
74140	Proxima® 2+ closed pouch with filter Beige diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000144ZM
74150	Proxima® 2+ closed pouch with filter Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000144ZM
74160	Proxima® 2+ closed pouch with filter Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000144ZM
74180	Proxima® 2+ closed pouch with filter Beige diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000144ZM
73340	Proxima® 2 drainable pouch without filter with clamp Beige diameter 40 mm by 30 units	Not Applicable	I	N	4039239000000147ZT
73350	Proxima® 2 drainable pouch without filter with clamp Beige diameter 50 mm by 30 units	Not Applicable	I	N	4039239000000147ZT
73360	Proxima® 2 drainable pouch without filter with clamp Beige diameter 60 mm by 30 units	Not Applicable	I	N	4039239000000147ZT
73380	Proxima® 2 drainable pouch without filter with clamp Beige diameter 80 mm by 30 units	Not Applicable	I	N	4039239000000147ZT
74340	Proxima® 2+ drainable pouch with filter Beige diameter 40 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74350	Proxima® 2+ drainable pouch with filter Beige diameter 50 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74360	Proxima® 2+ drainable pouch with filter Beige diameter 60 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74380	Proxima® 2+ drainable pouch with filter Beige diameter 80 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74440	Proxima® 2+ drainable pouch with filter Transparent diameter 40 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74450	Proxima® 2+ drainable pouch with filter Transparent diameter 50 mm by 10 units	Not Applicable	I	N	4039239000000146ZR

Référence / Article number	Designation	Certificat(s) CE / EC Certificate(s)	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
74460	Proxima® 2+ drainable pouch with filter Transparent diameter 60 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
74480	Proxima® 2+ drainable pouch with filter Transparent diameter 80 mm by 10 units	Not Applicable	I	N	4039239000000146ZR
73540	Proxima® 2 Urostomy pouch Transparent diameter 40 mm by 10 or 30 units	Not Applicable	I	N	4039239000000148ZV
73550	Proxima® 2 Urostomy pouch Transparent diameter 50 mm by 10 or 30 units	Not Applicable	I	N	4039239000000148ZV
73560	Proxima® 2 Urostomy pouch Transparent diameter 60 mm by 10 or 30 units	Not Applicable	I	N	4039239000000148ZV

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 2p 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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