

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)

Almarys Twin+ / Almarys PreferenceDestination : Système de recueil 2-pièces Supports Standards,
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, 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)

Almarys Twin+ / Almarys PreferenceIntended purpose: 2-piece collection system Base Plates
Standard, 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**
2026-12-31Saint-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
73040RU	Almarys® Preference Two-piece Base plates diameter 40 mm cut-to-fit by 10 units	Not applicable	I non sterile	N	403923900000202ZA
73050RU	Almarys® Preference Two-piece Base plates diameter 50mm cut-to-fit by 10 units	Not applicable	I non sterile	N	403923900000202ZA
73060RU	Almarys® Preference Two-piece Base plates diameter 60mm cut-to-fit by 10 units	Not applicable	I non sterile	N	403923900000202ZA
73080RU	Almarys® Preference Two-piece Base plates diameter 80mm cut-to-fit by 10 units	Not applicable	I non sterile	N	403923900000202ZA
74140RU	Almarys® Preference closed pouch with filter Beige diameter 40 mm by 30 units	Not applicable	I non sterile	N	403923900000203ZC
74150RU	Almarys® Preference closed pouch with filter Beige diameter 50 mm by 30 units	Not applicable	I non sterile	N	403923900000203ZC
74160RU	Almarys® Preference closed pouch with filter Beige diameter 60 mm by 30 units	Not applicable	I non sterile	N	403923900000203ZC
74180RU	Almarys® Preference closed pouch with filter Beige diameter 80 mm by 30 units	Not applicable	I non sterile	N	403923900000203ZC
74340RU	Almarys® Preference drainable pouch with filter Beige diameter 40 mm by 30 units	Not applicable	I non sterile	N	403923900000204ZE
74350RU	Almarys® Preference drainable pouch with filter Beige diameter 50 mm by 30 units	Not applicable	I non sterile	N	403923900000204ZE
74360RU	Almarys® Preference drainable pouch with filter Beige diameter 60 mm by 30 units	Not applicable	I non sterile	N	403923900000204ZE
74380RU	Almarys® Preference drainable pouch with filter Beige diameter 80 mm by 30 units	Not applicable	I non sterile	N	403923900000204ZE
73540RU	Almarys® Twin+ Urostomy pouches Transparent diameter 40 mm by 30 units	Not applicable	I non sterile	N	403923900000200Z6
73550RU	Almarys® Twin+ Urostomy pouches Transparent diameter 50 mm by 30 units	Not applicable	I non sterile	N	403923900000200Z6
73560RU	Almarys® Twin+ Urostomy pouches Transparent diameter 60 by 30 units	Not applicable	I non sterile	N	403923900000200Z6

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 Creation of references as per change control OM-CHC-FR09-55 for Almarys Preference sale extension (74140RU, 74150RU, 74160RU, 74180RU, 74340RU, 74350RU, 74360RU, 74380RU, 73540RU, 73550RU, 73560RU)
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	Removal of article number for phase out of Almarys Twin+ products as per change control: OM-CHC-FR09-48, OM-CHC-FR09-56, OM-CHC-FR09-67, OM-CHC-FR09-68, OM-CHC-FR09-PQ-10 and OM-CHC-FR09-152 ; Update of date of validity as per #313578

Title: Déclaration EU conformité MDR - Almarys Twin+ & Almarys Preference 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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Meaning: Document signed as Author

UserName: Schneider Ponsot, Manuelle (schnmafr)
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Date: Friday, 15 December 2023, 10:16 W. Europe Daylight Time
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