

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 : 40392390000015925

FLOW COLLECTORDestination : Poche collectrice à distance vidangeable pour
selles liquides Haut débit
(numéros d'article voir annexe I)

Fabriqué à

B. BRAUN MEDICAL SAS

13 rue Croix la Comtesse, 28400 Nogent-le-Rotrou, 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**

2003-01

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 : 40392390000015925

FLOW COLLECTORIntended purpose: distal Drainable collecting system for High
Flow liquid stools
(article numbers see attachment I)

Manufactured in

B. BRAUN MEDICAL SAS

13 rue Croix la Comtesse, 28400 Nogent-le-Rotrou, 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**

2003-01

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
039900	Flow Collector - Drainable collection system for high flow liquid stools 2L Transparent/white by 15 units	Not Applicable	I	N	403923900000015925
39900	Flow Collector - Drainable collection system for high flow liquid stools 2L Transparent/white by 15 units	Not Applicable	I	N	403923900000015925
039901	Flow Collector - Drainable collection system for high flow liquid stools 2L Transparent/white by 5 units	Not Applicable	I	N	403923900000015925

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	Edition as per ISO 13485 certificate No Q5 022239 0095 Rev. 02

Title: Flow Collector - Declaration EU of Conformity MDR Initiator: Isabelle Desplat

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

UserName: Desplat, Isabelle (despisfr)
Title: Regulatory Affairs Officer
Date: Wednesday, 29 September 2021, 11:40 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Buono, Laurent (buonlafr)
Title: Site Director
Date: Wednesday, 29 September 2021, 11:52 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Schneider-Ponsot, Manuelle (schnmafr)
Title: Quality Director / Safety Officer / Resp Pharmacist
Date: Monday, 04 October 2021, 09:32 W. Europe Daylight Time
Meaning: Approve Document
=====