



medCOMP

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EC/CE DECLARATION OF CONFORMITY

DoC-002

Manufacturer:	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Single Registration Number (SRN):	US-MF-000008230
Notified Body:	BSI Group the Netherlands B.V. Notified Body No. 2797
Authorized Representative:	MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels, Germany SRN: DE-AR-000005009
EC Certificate Number:	MDR 759413 and MDR 734734
Conformity Assessment:	Per Annex IX (Chapters I, II and III)
Product Brand/Trade Name:	Hemo-Flow® Double Lumen Catheter Sets, Jet Flow Double Lumen Catheter Sets, & Nipro Flow Double Lumen Catheter Sets
Product Intended Purpose:	Hemo-Flow®, Jet Flow and Nipro Flow Catheters are intended for use in adult patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. • This catheter is for Single Use Only.
Device Classification:	Class III, Rule 8, per Annex VIII
Device Identification:	See Appendix A
Additional Information:	See Appendix B

We, Medcomp, hereby declare, under our sole responsibility, that the above-mentioned device complies with the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and their relevant transposition into national laws of the Member States in which the above-mentioned device(s) are distributed.

Martina Arno
Regulatory Affairs North America and Europe
Medical Components, Inc.
1499 Delp Drive
Harleysville PA, 19438
USA

10NOV2022

Effective Date



Appendix A

The following listed product models are compliant to the requirements stated on Page 1.

Hemo-Flow® Double Lumen Hemodialysis Catheter Sets [Class III]			
Catalog Code	Part Number	Description	Basic UDI-DI
HFS24E.	10385-824-001	14.5F x 24cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)	00884908101MG
HFS28E.	10385-828-001	14.5F x 28cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)	00884908101MG
HFS32E.	10385-832-001	14.5F x 32cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)	00884908101MG
HFS36E.	10385-836-001	14.5F x 36cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)	00884908101MG
HFS 55	10385-855-001	14.5F x 55cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 50cm From Tip)	00884908101MG
HFS40E.	10385-840-001	14.5F x 40cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)	00884908101MG
HFS24PCE.	10385-824-001C	14.5F x 24cm Hemo-Flow® Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 19cm From Tip)	00884908101MG
HFS28PCE.	10385-828-001C	14.5F x 28cm Hemo-Flow® Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 23cm From Tip)	00884908101MG
HFS32PCE.	10385-832-001C	14.5F x 32cm Hemo-Flow® Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 27cm From Tip)	00884908101MG
HFS36PCE.	10385-836-001C	14.5F x 36cm Hemo-Flow® Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 31cm From Tip)	00884908101MG

Jet Flow Double Lumen Hemodialysis Catheter Sets [Class III]			
Catalog Code	Part Number	Description	Basic UDI-DI
JFC1424	10385-824-100	14.5F x 24cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)	00884908101MG
JFC1428	10385-828-100	14.5F x 28cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)	00884908101MG
JFC1432	10385-832-100	14.5F x 32cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)	00884908101MG
JFC1436	10385-836-100	14.5F x 36cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)	00884908101MG
JFC1440	10385-840-100	14.5F x 40cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)	00884908101MG
JFC1424PC	10385-824-100C	14.5F x 24cm Jet Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 19cm From Tip)	00884908101MG
JFC1428PC	10385-828-100C	14.5F x 28cm Jet Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 23cm From Tip)	00884908101MG
JFC1432PC	10385-832-100C	14.5F x 32cm Jet Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 27cm From Tip)	00884908101MG

Nipro Flow Double Lumen Hemodialysis Catheter Sets [Class III]			
Catalog Code	Part Number	Description	Basic UDI-DI
NITDL24SK	10385-824-112	14.5F x 24cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)	00884908101MG
NITDL28SK	10385-828-112	14.5F x 28cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)	00884908101MG
NITDL32SK	10385-832-112	14.5F x 32cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)	00884908101MG
NITDL36SK	10385-836-112	14.5F x 36cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)	00884908101MG
NITDL24CK	10385-824-112C	14.5F x 24cm Nipro Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 19cm From Tip)	00884908101MG
NITDL28CK	10385-828-112C	14.5F x 28cm Nipro Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 23cm From Tip)	00884908101MG
NITDL32CK	10385-832-112C	14.5F x 32cm Nipro Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 27cm From Tip)	00884908101MG
NITDL36CK	10385-836-112C	14.5F x 36cm Nipro Flow Double Lumen Hemodialysis Pre-Curved Catheter Set (Cuff 31cm From Tip)	00884908101MG

Appendix B

Common Specifications (CS), where applicable, are listed in the table below.

Common Specifications			
Common Specification Reference	Revision	Description	Compliance (Full/Partial)
This product does not have common specifications.			

REVISION HISTORY

Revision Level	Date Revised	Reason for change to DoC	CR#
A	08 NOV 2022	Initial release of the Declaration of Conformity	27405