

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 759413 R000

**Manufacturer:** Medical Components Inc.

**Address:**

1499 Delp Drive  
Harleysville  
Pennsylvania  
19438  
USA

**Single Registration Number:** US-MF-000008230

**EU Authorised Representative:** MPS Medical Product Service GmbH

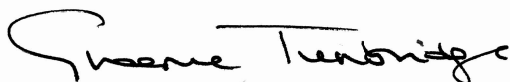
**Address:**

Borngasse 20  
35619 Braunfels  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-08**

Current Issue Date: **2022-11-08**

Starting Validity Date: **2022-11-08**

Expiry Date: **2027-11-07**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 759413 R000

### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

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.

**Risk Classification:** Class III Implantable

**Basic UDI-DI:** 00884908101MG

**Type (Codes as per (EU) 2017/2185):** MDN 1101

Model	Device Name
<b>Hemo-Flow® Catheter Catheter Sets</b>	
HFS24E.	14.5F x 24cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)
HFS28E.	14.5F x 28cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)
HFS32E.	14.5F x 32cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)
HFS36E.	14.5F x 36cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)
HFS40E.	14.5F x 40cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)
HFS 55	14.5F x 55cm Hemo-Flow® Double Lumen Hemodialysis Catheter Set (Cuff 50cm From Tip)

First Issue Date: **2022-11-08**

Current Issue Date: **2022-11-08**

Starting Validity Date: **2022-11-08**

Expiry Date: **2027-11-07**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 759413 R000

Model	Device Name
<b>Hemo-Flow® Catheter (Pre-Curved Lumen) Catheter Sets</b>	
HFS24PCE.	14.5F x 24cm Hemo-Flow® Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 19cm From Tip)
HFS28PCE.	14.5F x 28cm Hemo-Flow® Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 23cm From Tip)
HFS32PCE.	14.5F x 32cm Hemo-Flow® Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 27cm From Tip)
HFS36PCE.	14.5F x 36cm Hemo-Flow® Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 31cm From Tip)
<b>Jet Flow Catheter (Straight) Catheter Sets</b>	
JFC1424	14.5F x 24cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)
JFC1428	14.5F x 28cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)
JFC1432	14.5F x 32cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)
JFC1436	14.5F x 36cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)
JFC1440	14.5F x 40cm Jet Flow Double Lumen Hemodialysis Catheter Set (Cuff 35cm From Tip)
<b>Jet Flow (Pre-Curved Lumen) Catheter Sets</b>	
JFC1424PC	14.5F x 24cm Jet Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 19cm From Tip)
JFC1428PC	14.5F x 28cm Jet Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 23cm From Tip)
JFC1432PC	14.5F x 32cm Jet Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 27cm From Tip)

First Issue Date: **2022-11-08**

Current Issue Date: **2022-11-08**

Starting Validity Date: **2022-11-08**

Expiry Date: **2027-11-07**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 759413 R000

Model	Device Name
<b>Nipro Flow Catheter (Straight) Catheter Sets</b>	
NITDL24SK	14.5F x 24cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 19cm From Tip)
NITDL28SK	14.5F x 28cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 23cm From Tip)
NITDL32SK	14.5F x 32cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 27cm From Tip)
NITDL36SK	14.5F x 36cm Nipro Flow Double Lumen Hemodialysis Catheter Set (Cuff 31cm From Tip)
<b>Nipro Flow Catheters (Pre-Curved Lumen) Catheter Sets</b>	
NITDL24CK	14.5F x 24cm Nipro Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 19cm From Tip)
NITDL28CK	14.5F x 28cm Nipro Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 23cm From Tip)
NITDL32CK	14.5F x 32cm Nipro Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 27cm From Tip)
NITDL36CK	14.5F x 36cm Nipro Flow Double Lumen Hemodialysis Pre- Curved Catheter Set (Cuff 31cm From Tip)

First Issue Date: **2022-11-08**

Current Issue Date: **2022-11-08**

Starting Validity Date: **2022-11-08**

Expiry Date: **2027-11-07**

...making excellence a habit.™

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

**MDR 759413 R000**

## Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))*

Date	Reference Number	Action
Current	3556539	Issued

First Issue Date: **2022-11-08**

Current Issue Date: **2022-11-08**

Starting Validity Date: **2022-11-08**

Expiry Date: **2027-11-07**

...making excellence a habit.™