EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	C. R. Bard, Inc. 8195 Industrial Boulevard Covington, GA 30014, USA
Manufacturer SRN:	US-MF-000018892
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	Flip-Flo™ Catheter Valve
Basic UDI-DI:	0801741HRKCMRXNXK
Risk Class and Rule:	Class I Sterile, per Annex VIII, Rule 1 of the European Medical Device Regulation (MDR) 2017/745
Intended Purpose	The Flip-Flo Catheter Valve is intended to facilitate urine drainage and/or collection. For urological use only.
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands Notified Body Number: 2797
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s): • Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices • Regulation (EU) 2021/2226 on Electronic Instructions for Use of Medical Devices	

Conformity Assessment Route:

☒ ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: **MDR 757642** Certificate Expiration Date: **November 20, 2027**
☐ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.:
☐ ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
☒ ANNEX II & III Technical Documentation	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:
N/A	N/A	N/A

The Common Specifications table is intentionally left blank, as no common specifications have been identified for the Flip Flo Catheter Valves.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
BFF5	Flip-Flo Catheter Valve (5 units)	I Sterile
BFF20	Flip-Flo Catheter Valve (20 units)	I Sterile
BXBFF5	Flip-Flo Catheter Valve, Benelux (5 units)	I Sterile

Authorised Signatory:	
Name & Title:	Michele Davis / VP Regulatory Affairs
On behalf of:	C. R. Bard, Inc.
Place of Issue:	8195 Industrial Boulevard Covington, GA 30014
Date of Issue:	16 October 2024
Signature:	Michele Davis
Authorised Signatory:	
Name & Title:	Elizabeth Gaipa / VP Quality Management
On behalf of:	C. R. Bard, Inc.
Place of Issue:	8195 Industrial Boulevard Covington, GA 30014
Date of Issue:	16 October 2024
Signature:	Elizabeth Gaipa

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
0	Original document to declare conformity to EU MDR