

**EU DECLARATION OF CONFORMITY (DoC)**

Manufacturer:	C. R. Bard, Inc. 8195 Industrial Boulevard Covington, Georgia 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:	Pop-On, WideBand, UltraFlex, and Transfix Male External Catheters
Basic UDI-DI:	0801741WJQSKQRHAQ
Risk Class and Rule:	Class I (non-sterile and non-measuring) per Annex VIII, Rule 1 of the European Medical Device Regulation (MDR) 2017/745
Intended Purpose	The self-adhering male external catheter is used for the drainage of urine. The catheter is applied by the patient or caregiver.
Notified Body:	Not applicable; the devices are Class I (non-sterile and non-measuring), thus they are self-certified. Notified Body is not required.
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) 2017/2012 on Electronic Instructions for Use of Medical Devices	

Conformity Assessment Route:

☐ ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: Certificate Expiration Date:
☐ ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: Certificate Expiration Date:
☐ 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:
Not Applicable	Not Applicable	Not Applicable

Devices Covered by this DoC:

SKU#	Device Name	Device Class
32101	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32102	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32103	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32104	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32105	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32301	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32302	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32303	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32304	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32305	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32301HP	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32302HP	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32303HP	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32304HP	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
32305HP	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032825	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032829	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.

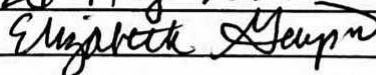
R05285032832	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032836	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032841	Pop-On Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36101	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36102	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36103	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36104	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36105	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36301	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36302	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36303	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
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36305	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36301HP	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
36302HP	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
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R05285032929	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032932	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032936	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.

R05285032941	Wideband Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33101	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33102	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33103	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33104	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33105	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
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33305	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33301HP	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33302HP	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
33303HP	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
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R05285032736	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
R05285032741	UltraFlex Self-Adhering Male External Catheter	Class I, non-sterile and non-measuring medical device.
TF12530	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.

TF12530NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF12930	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF12930NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF13230	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF13230NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF13630	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF13630NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF14130	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF14130NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF22530	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF22530NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF22930	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF22930NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF23230	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF23230NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF23630	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF23630NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF24130	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF24130NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF32530	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF32530NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF32930	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.



TF32930NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF33230	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF33230NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF33630	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF33630NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF34130	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.
TF34130NHS	Transfix All-Silicone Self-Adhesive Continence Sheath	Class I, non-sterile and non-measuring medical device.

Authorized Signatory:	
Name & Title:	Michele Davis, VP of Regulatory Affairs
On behalf of:	C. R. Bard, Inc.
Place of Issue:	8195 Industrial Boulevard Covington, GA 30014, USA
Date of Issue:	25 Aug 2022
Signature:	
Name & Title:	Elizabeth Gaipa, VP of Quality Assurance
On behalf of:	C. R. Bard, Inc.
Place of Issue:	8195 Industrial Boulevard Covington, GA 30014, USA
Date of Issue:	26 Aug 2022
Signature:	

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
0	Original document to declare conformity to EU MDR
1	Updated Authorized Representative Information and approval personnel. Updated to current version of form (rev. 3)
2	Updated SRN information and authorized signatory information for quality management. Added Regulation (EU) 207/2012 on Electronic Instructions for Use of Medical Devices. Updated to current revision of the form (rev 5).

**TEMPLATE Revision History:**

Rev	Revision Description	ECO Number	Requested By
05	Updated Authorized Signatory section to include a box with the statement "On behalf of" as well as provide guidance/instructions. This requirement MDR requirement for the DoC was missed in the Revision 4 update.	500000285045	Terri Krutz
04	Updated to include Chapter III in conformity assessment route option "ANNEX IX Chapter I – Quality management System" for all languages. Modified header to include Version Number as some businesses use SAP and others may use other approval and storage systems	500000283041	C. Pell
03	Updated to include Intended Purpose and guidance. Updated Revision History in Footer.	500000230219	David Pieratos
02	Based on recommendations from the BDX European Regulatory Affairs team, the DoC was reformatted to simplify the content to be in line with 2017/745 and MedTech Europe Guidance.	500000213116	Denise Oliveira
01	Original release.	500000190393	Jennifer Jaye

Signature Manifest

Document Number: DC030181

Revision: 2

Title: Declaration of Conformity for Pop-On, WideBand, UltraFlex, and Transfix Male External Catheters TD181 (EU MDR)

All dates and times are in Eastern Standard Time.

MDR Declaration of Conformity Updates to rev5 Form for Male External Catheters

Doc Control Check

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Quality Doc Sys Mgmt Supvr		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II	02 Sep 2022, 08:38:09 AM	Approved

Assign Approvers/Modify

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Tisha Miles (TMILES)	Quality Doc Sys Mgmt Supvr		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II	02 Sep 2022, 08:38:25 AM	Complete

Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Matthew Rather (MRATHER)	RA Associate	02 Sep 2022, 10:05:06 AM	Approved

DC Final Review

Name/Signature	Title	Date	Meaning/Reason
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Tisha Miles (TMILES)	Quality Doc Sys Mgmt Supvr		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Sasha Sims (SSIMS)	Document Control Lead	06 Sep 2022, 04:34:08 PM	Complete

CR Final Release

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Name/Signature	Title	Date	Meaning/Reason
Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Tisha Miles (TMILES)	Quality Doc Sys Mgmt Supvr		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Sasha Sims (SSIMS)	Document Control Lead	06 Sep 2022, 04:37:17 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Matthew Rather (MRATHER)	RA Associate	06 Sep 2022, 04:37:19 PM	Email Sent

Development Released