Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, Georgia 30014 USA

BARD

DECLARATION OF CONFORMITY

DC Number: DC030052 **Revision:** 11

C. R. Bard, Inc.

located at:
8195 Industrial Boulevard
Covington, Georgia 30014 USA,

does hereby declare that the Bard® and Uriplan™ Leg Bags and Accessories, which consists of the device catalog number(s) referenced on the attached list, meets the provisions and requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD). The CE marking has been affixed in accordance with article 17 of the MDD.

Classification (MDD, Annex IX, Rule 1): Class I Sterile meeting Annex V and receipt of CE Certificate from Notified Body.

Notified Body:

BSI Product Services (ID # 2797)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

C. R. Bard, Inc.'s Authorized Representative is:

BD Switzerland Sàrl
Terre Bonne Park - A4
Route de Crassier 17
1262 Eysins,
Switzerland

B Newton for Mark Neal
VP Quality Assurance, Mark Neal

09 Jan 2020
Date

Michele Davis
Director Regulatory Affairs, Michele Davis

7 Jan 2020
Date

DECLARATION OF CONFORMITY

DC Number: DC030052 Revision: 11

PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
000538	Uriplan™ Sheath Adapter Tubing	31975	Urethral/ureteral catheter connector, sterile
150101	Dispoz-A-Bag Leg Bag, Small, 9oz	58923	Open-ended wearable urine collection bag, sterile
150102	Dispoz-A-Bag Leg Bag, Medium, 19oz	58923	Open-ended wearable urine collection bag, sterile
150103	Dispoz-A-Bag Leg Bag, Large, 32oz	58923	Open-ended wearable urine collection bag, sterile
3L	Uriplan™ Leg Bag, 350ml long tube	58923	Open-ended wearable urine collection bag, sterile
3S	Uriplan™ Leg Bag, 350ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
5L	Uriplan™ Leg Bag, 500ml long tube	58923	Open-ended wearable urine collection bag, sterile
5M	Uriplan™ Leg Bag, 500ml short tube	58923	Open-ended wearable urine collection bag, sterile
5S	Uriplan™ Leg Bag, 500ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
7664	Urisac Leg Bag	58923	Open-ended wearable urine collection bag, sterile
7665	Urisac Leg Bag	58923	Open-ended wearable urine collection bag, sterile
7L	Uriplan™ Leg Bag, 750ml long tube	58923	Open-ended wearable urine collection bag, sterile
7LX	Uriplan™ Leg Bag, 750ml extra long tube	58923	Open-ended wearable urine collection bag, sterile
7M	Uriplan™ Leg Bag, 750ml short tube	58923	Open-ended wearable urine collection bag, sterile
7S	Uriplan™ Leg Bag, 750ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
B350L	Bardia® Leg Bag, 350ml long tube	58923	Open-ended wearable urine collection bag, sterile

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
B350S	Bardia® Leg Bag, 350ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
B500L	Bardia® Leg Bag, 500ml long tube	58923	Open-ended wearable urine collection bag, sterile
B500M	Bardia® Leg Bag, 500ml short tube	58923	Open-ended wearable urine collection bag, sterile
B500S	Bardia® Leg Bag, 500ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
B750L	Bardia® Leg Bag, 750ml long tube	58923	Open-ended wearable urine collection bag, sterile
B750LX	Bardia® Leg Bag, 750ml extra long tube	58923	Open-ended wearable urine collection bag, sterile
B750M	Bardia® Leg Bag, 750ml short tube	58923	Open-ended wearable urine collection bag, sterile
B750S	Bardia® Leg Bag, 750ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
BFF20	Bard® Flip-Flo™ Catheter Valve	31975	Urethral/ureteral catheter connector, sterile
BFF5	Bard® Flip-Flo™ Catheter Valve	31975	Urethral/ureteral catheter connector, sterile
BX3L	Uriplan™ Leg Bag, 350ml long tube, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX3S	Uriplan™ Leg Bag, 350ml direct inlet, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX5L	Uriplan™ Leg Bag, 500ml long tube, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX5M	Uriplan™ Leg Bag, 500ml short tube, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX5S	Uriplan™ Leg Bag, 500ml direct inlet, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX7L	Uriplan™ Leg Bag, 750ml long tube, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX7LX	Uriplan™ Leg Bag, 750ml extra long tube, Benelux	58923	Open-ended wearable urine collection bag, sterile

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
BX7M	Uriplan™ Leg Bag, 750ml short tube, Benelux	58923	Open-ended wearable urine collection bag, sterile
BX7S	Uriplan™ Leg Bag, 750ml direct inlet, Benelux	58923	Open-ended wearable urine collection bag, sterile
BXBFF5	Bard® Flip-Flo™ Catheter Valve, Benelux	31975	Urethral/ureteral catheter connector, sterile
D3L	Uriplan™ Leg Bag, 350ml long tube	58923	Open-ended wearable urine collection bag, sterile
D3S	Uriplan™ Leg Bag, 350ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
D5L	Uriplan™ Leg Bag, 500ml long tube	58923	Open-ended wearable urine collection bag, sterile
D5M	Uriplan™ Leg Bag, 500ml short tube	58923	Open-ended wearable urine collection bag, sterile
D5S	Uriplan™ Leg Bag, 500ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
D7L	Uriplan™ Leg Bag, 750ml long tube	58923	Open-ended wearable urine collection bag, sterile
D7LX	Uriplan™ Leg Bag, 750ml extra long tube	58923	Open-ended wearable urine collection bag, sterile
D7M	Uriplan™ Leg Bag, 750ml short tube	58923	Open-ended wearable urine collection bag, sterile
D7S	Uriplan™ Leg Bag, 750ml direct inlet	58923	Open-ended wearable urine collection bag, sterile
IT3L	Uriplan™ Leg Bag, 350ml long tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT3S	Uriplan™ Leg Bag, 350ml direct inlet, Italy	58923	Open-ended wearable urine collection bag, sterile
IT5L	Uriplan™ Leg Bag, 500ml long tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT5M	Uriplan™ Leg Bag, 500ml short tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT5S	Uriplan™ Leg Bag, 500ml direct inlet, Italy	58923	Open-ended wearable urine collection bag, sterile

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DC Number: DC030052 **Revision: 11**

PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
IT7L	Uriplan™ Leg Bag, 750ml long tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT7LX	Uriplan™ Leg Bag, 750ml extra long tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT7M	Uriplan™ Leg Bag, 750ml short tube, Italy	58923	Open-ended wearable urine collection bag, sterile
IT7S	Uriplan™ Leg Bag, 750ml direct inlet, Italy	58923	Open-ended wearable urine collection bag, sterile

DECLARATION OF CONFORMITY

DC Number: DC030052 **Revision: 11**

REVISION HISTORY

REV. #	CR #	DESCRIPTION
0	TechFile#73	Created Declaration of Conformity for Drainage Bags that were transferred from the Clacton manufacturing facility to either the Nogales or Malaysia manufacturing facility.
1	TechFile#112	Updated Declaration of Conformity to include the note regarding the "0", "BX" and "Ir variations to some of the codes.
2	TechFile#124	Updated Declaration of Conformity to correct typographical errors.
3	TechFile#222	Updated DoC to add new Code (B2000UK) supporting Project 764946
4	TechFile#368	Updated to use new Declaration of Conformity form FM0301166. Removed Bed Bag codes 813131,82000, B2000UK & 0813131 (to be included in TF#7 DOC). Removed 811535ST as it was discontinued in 2006.
5	TechFile#500	Updated DoC to correct product code 000538 which was listed as 0538.
6	BM-COV-CR01487	Updated document to reflect FM0301166 Rev. 2. Added ® to Uriplan and Flip-Flo to reflect proper trademarks.
7	BM-COV-CR-02045	Revised document to correct the note regarding variations to some of the codes to include “BX” and “IT” as CE compliant, and to include Benelux and Italy respectively.
8	BM-COV-CR-02095	Revised document to correct the annotated code in the Note from “0” to “D”. This was a typo from Rev 1.
9	BM-COV-CR-03477	Updated to new revision of FM0301166 Rev.3. Removed 65/65/EEC as Medicinal Directive does not apply. Updated obsolete GMDN code/term for leg bags from 31085 to 58923. Also updated obsolete GMDN code/term for Sheath Adapter and Flip Flo from 14247 & 31085 to 31975.
10	BM-COV-CR-07288	Updated Notified Body information.

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DC Number: DC030052 **Revision: 11**

11	BM-PROJ-CR-22659	Updated to document FM0301166 Revision 5; updated Authorized Representative Information and approval personnel. Added variants of some of the above product codes, annotated with "BX" and "IT" prefixes (BX3L-BXBFF5, IT3L-IT7S). Removed variants note from end of product code table. Added product codes 150101, 150102, 150103. Clarified product description in the declaration section.

Signature Manifest

Document Number: DC030052 **Revision:** 11

Title: Declaration of Conformity for Techncial File 52, Drainage Bags & Accessories

All dates and times are in Eastern Standard Time.

DoC Update - TF52

Doc Control Check

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
Jaimie Mowers (JMOWERS)	QA Specialist/Doc Control		
Jessica Latimore (JLATIMORE)	Training Coordinator III		
Sasha Sims (SSIMS)	Document Control Lead		
Yasmin Roman (YROMAN)	Doc. Control Analyst		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Rachel Harms (RHARMS)	Documentation Specialist	21 May 2020, 12:05:58 PM	Approved

Assign Approvers/Modify

Name/Signature	Title	Date	Meaning/Reason
Rachel Harms (RHARMS)	Documentation Specialist	21 May 2020, 12:07:38 PM	Complete

Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Dana Abdelal (DABDELAL)	RA Specialist	02 Jun 2020, 08:36:56 AM	Approved

DC Final Review

Name/Signature	Title	Date	Meaning/Reason
Yasmin Roman (YROMAN)	Doc. Control Analyst		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Jaimie Mowers (JMOWERS)	QA Specialist/Doc Control		
Jessica Latimore (JLATIMORE)	Training Coordinator III		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead	02 Jun 2020, 11:22:17 AM	Complete

CR Final Release

Name/Signature	Title	Date	Meaning/Reason
Jaimie Mowers (JMOWERS)	QA Specialist/Doc Control		
Jessica Latimore (JLATIMORE)	Training Coordinator III		
Rachel Harms (RHARMS)	Documentation Specialist		
Yasmin Roman (YROMAN)	Doc. Control Analyst		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		

Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Sasha Sims (SSIMS)	Document Control Lead	02 Jun 2020, 11:48:32 AM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Dana Abdelal (DABDELAL)	RA Specialist	02 Jun 2020, 11:48:34 AM	Email Sent

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 515494**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

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By Royal Charter

Certificate No: CE 515494

Certificate Scope:

Manufacture of sterile Foley catheters and accessories (including procedural kits and trays), urethral/intermittent catheters and accessories, ureteral catheter and accessories, gastrointestinal tubes, respiratory care products and wound suction/drainage products.

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of urethral/intermittent catheters and accessories, ureteral catheter and accessories, mucous specimen devices, ureteroscopic and kidney stone removal devices including cystoscopic irrigation bags and graspers and accessories (ureteral stent accessory), securement devices for catheters, bladder evacuation products, irrigation syringes, wound suction/drainage products, urinary drainage bags (including leg bags) and collection container/systems.

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 515494

Issued To:

C.R. Bard, Inc.
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Foley Catheters and Accessories (Including Procedural Kits and Trays)	---
MD 0102	Urethral/Intermittent Catheters and Accessories	---
MD 0102	Urethral Catheter and Accessories	---
MD 0102	Gastrointestinal Tubes	---
MD 0101	Respiratory Care Products	---
MD 0303	Wound Suction/Drainage Products	---

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 515494

Issued To:

C.R. Bard, Inc.
8195 Industrial Blvd.
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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0102	Urethal/Intermittent Catheters and Accessories	---
MD 0102	Ureteral Catheter and Accessories	---
MD 0106	Ureteral Catheter and Accessories	---
MD 0102	Mucous Specimen Devices	---
MD 0106	Ureteroscopic and Kidney Stone Removal Devices and Accessories (Including Cystoscopic Irrigation Bags and Graspers)	---
MD 0102	Securement Devices for Catheters	---
MD 0106	Bladder Evacuation Products	---
MD 0102	Irrigation Syringes	---
MD 0303	Wound Suction/Drainage Products	---
MD 0102	Urinary Drainage Bags (Including Leg Bags)	---
MD 0102	Collection Containers/Systems	---

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
12 April 2007	7814681	First Issue based on a subset of CE 00931.
3 October 2007		Addition of Integra Biotechnical LLC, Vista, California as a manufacturing subcontractor.
16 October 2009	7399834	Amendment to scope of certification for devices transferred from CE 515497. Addition of Bard Reynosa as a significant subcontractor.
26 February 2010	7482085	Extension to scope. Amendment to scope of certification for devices transferred from CE 515497. Addition of Bard Limited, Crawley as EU Rep.
29 March 2012	7816995	Certificate renewal.
19 November 2015	8414283	Extension of scope to include e-beam sterilisation, addition of significant subcontractor Rochester Medical Corporation at One Rochester Medical Drive and 455 Rochester Medical Drive; addition of Synergy Health AST, LLC, Denver Colorado.
12 August 2016	8586084	Addition of significant subcontractor Synergy Health AST LLC, Lima, Ohio.

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
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Date	Reference Number	Action
11 April 2017	8675581	Certificate renewal. Removal of subcontractor Integra Biotechnical LLC. Removal of sterilization activity by the subcontractor Davol Surgical Innovations S.A. de C.V. Addition of subcontractors Futurematrix Interventional, Athens, Texas; Omnitech Systems, Valparaiso, Indiana; Atrion Medical Products, Inc., Arab, Alaba; all for the activities manufacture and packaging.
21 December 2017	8849591	Addition of significant subcontractor for ETO sterilization, Sterigenics Belgium (Petit-Rechain) SA.
2 May 2018	8921549	Addition of significant subcontractor Iotron Industries USA for E Beam Sterilization. Addition of significant subcontractor Isomedix Operations, Inc. site in Ontario, California for E Beam Sterilization.
25 February 2019	7781192	Traceable to NB 0086.
18 December 2019	3081405	Update of EU Rep. to BD Switzerland Sarl.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
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Date	Reference Number	Action
25 September 2020	3065608	Certificate Renewal Removal of scope – urinary drainage bags (including leg bags) and collection containers/systems (including volume measurement), urological guidewire and dilation products, irrigation syringes and accessories, ureteroscopic and kidney stone removal devices and accessories, Fecal and urinary incontinence; Ostomy products and accessories; metrology and volume measurements Modifying accessories listed as "including cystoscopic irrigation bags and graspers" to be included as device for ureteroscopic and kidney stone removal and specifying accessories as 'ureteral stent accessory' Merging of the Annex V scope related to sterility aspects into 1 paragraph Removal of subcontractors – Rochester Medical Corporation and Synergy Health AST Addition of subcontractors – Bard Regional Sterilization Facility, Smart World LLC, and Sterigenics US LLC in 3125 Wichita Court, Fort Worth, Texas Added "Control of Sterilization" service to Bard Sdn. Bhd., Kedah, Malaysia

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**
Date: **2020-09-25**
Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
		Subcontractor address update for Bard Reynosa to "Blvd. Montebello No. 1, Parque Industrial Colonial, Reynosa, Tamaulipas, Mexico" Subcontractor name/address update for Bard Medical Division, Nogales, Mexico to "C. R. Bard Inc. PRODUCTOS PARA EL CUIDADO DE LA SALUD Carretera Internacional KM 6.5, Terrazas del Cid Nogales, Sonora, 84000, Mexico". Administrative update to add product supplementary table per MDP4500. Administrative update to spell out "Boulevard" in LM address Addition of gamma sterilization for Intermittent Catheters
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 May 2023	3891029	Change in EU Authorized Representative from "BD Switzerland Sarl" to "Beckton Dickinson Limited Ireland"

Inspiring trust for a more resilient world.

30 May 2023

C.R. Bard, Inc.
8195 Industrial Blvd.
Covington
Georgia
30014
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 515494	93/42/EEC Annex V	3891029	Change in EU Authorized Representative from "BD Switzerland Sarl" to "Beckton Dickinson Limited Ireland"

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices