

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



DECLARATION OF CONFORMITY

DC Number: DC030053

Revision: 10

C. R. Bard, Inc.

located at:
8195 Industrial Boulevard
Covington, Georgia 30014 USA

does hereby declare that the Bard® All Silicone Foley Catheters, 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 5 & 8): Class IIb meeting Annex II and receipt of CE Certificate from the 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:

Becton Dickinson Ireland Ltd.
Donore Road, Drogheda
Co. Louth, A92 YW26
Ireland


VP Quality Assurance, Mark Neal

19 Nov 2021

Date


VP Regulatory Affairs, Michele Davis

22 Nov 2021
Date

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
165808CE	Bard® All-Silicone Foley Catheter, Pediatric length with 5ml balloon	34917	Catheter, urological, self-retained
165810CE	Bard® All-Silicone Foley Catheter, Pediatric length with 5ml balloon	34917	Catheter, urological, self-retained
165812CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165814CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165816CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165818CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165820CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165822CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
165824CE	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165808	Bard® All-Silicone Foley Catheter, Pediatric length with 5ml balloon	34917	Catheter, urological, self-retained
BX165810	Bard® All-Silicone Foley Catheter, Pediatric length with 5ml balloon	34917	Catheter, urological, self-retained
BX165812	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165814	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
BX165816	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165818	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165820	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165822	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
BX165824	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165812	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165814	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165816	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165818	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165820	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
D165822	Bard® All-Silicone Foley Catheter, Male length with 10ml balloon	34917	Catheter, urological, self-retained
166112CE	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained
166114CE	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
166116CE	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained
D166112	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained
D166114	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained
D166116	Bard® All-Silicone Foley Catheter, Female length with 10ml balloon	34917	Catheter, urological, self-retained
166816CE	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166818CE	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166820CE	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166822CE	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166824CE	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166816UK	Bardia® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166818UK	Bardia® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166820UK	Bardia® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
166822UK	Bardia® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
166824UK	Bardia® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
BX166816	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
BX166818	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
BX166820	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
BX166822	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
D166816	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
D166818	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
D166820	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained
D166822	Bard® All-Silicone Foley Catheter, Male length with 30ml balloon	34917	Catheter, urological, self-retained

NOTE: There are variants of some of the above product codes, annotated "D" and "BX",. These are CE compliant, country specific variants for UK, Benelux, Italy and France, respectively. Such variants may not comply with the language requirements of all EU countries.

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REVISION HISTORY

<u>REV. #</u>	<u>CR #</u>	<u>DESCRIPTION</u>
0	TechFile#(74)	Created Declaration of Conformity for the All-Silicone Foley Catheters that were transferred from the Clacton manufacturing facility to the either the Nogales or Malaysia manufacturing facility.
1	TechFile#(124)	Updated Declaration of Conformity to correct typographical errors and to add note regarding variants on some of the product codes.
2	TechFile#(190)	Changed from Bard Limited address (Crawley) to Bard Medical address (Covington)
3	TechFile#(238)	Item code BX266816-22 had to be changed to BS166816-22. Item codes 1658XXCE and 1668XXCE were added.
4	TechFile#(342)	Changed the manufacturer listed from Bard Limited to C.R. Bard, Inc. with Covington address and added bard Limited as the Authorized Representative.
		Updated to new form. Added D166824, 166112CE, 166114CE and 166116CE. Removed 165808-165810, 165812-165824, 166112-166116, 166816-166824, D166118-D166122, IT166812, IT166814, IT166824 as they are no longer active codes for the EU. Updated the NOTE to include France and noted the variants may not comply with language requirement.
5	BM-COV-CR-01330	Updated document to reflect FM0301166 Rev. 2. Corrected Rule Classification. Added ® to Bard to reflect proper trademarks.
6	BM-COV-CR-02714	Add USA and Georgia to the letterhead and body. Add names to the signature lines. Correct minor grammar errors.
7	BM-COV-CR-03906	Added product code 166824CE after confirming compliance. Removed reference to Council Directive 65/65/EEC relating to medicinal products (MEDDEV 2.1/3, Rev. 2, July, 2001) as this does not apply to these product codes.
8	BM-COV-CR-07308	Updated document to remove discontinued product codes per CSA's. <ul style="list-style-type: none">• CSA-87-5077-1:<ul style="list-style-type: none">• D165824• D166824• CSA-03-1931-1<ul style="list-style-type: none">• F165812 – F165824• IT165812 – IT 165824• IT166112 – IT166116• IT166816 – IT166822

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Updated Note at the end of Product Code List Table to

remove "IT" and "F" designations as there are not more product codes in this Tech File preceding with "IT" or "F" designations per CSA-03-1931-1.

Updated to new form which included updates to Notified Body information and approval personnel.

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|----|-----------------|--|
| 9 | BM-COV-CR-07659 | Updated to new form which included update to Authorized Representative Information and approval personnel. |
| 10 | BM-COV-CR-10106 | Updated to reflect FM0301166 Revision 6 which included update to Authorized Representative Information and approval personnel. |

Signature Manifest

Document Number: DC030053

Revision: 10

Title: Declaration of Conformity for Technical File 53 All-Silicone Foley Catheters

All dates and times are in Eastern Standard Time.

BM-COV-CR-10106 DoC Updates

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		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tisha Miles (TMILES)	Engr 3, Quality Assurance	24 Nov 2021, 01:39:41 PM	Approved

Assign Approvers/Modify

Name/Signature	Title	Date	Meaning/Reason
DEEPAN KARNAN (DKARNAN)	R&D Engineer Temp - HCL		
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Jessica Latimore (JLATIMORE)	Document Control Coordinator		
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Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tisha Miles (TMILES)	Engr 3, Quality Assurance	24 Nov 2021, 01:40:23 PM	Complete

Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Rebecca Bigby (10295664)	RA Associate	02 Dec 2021, 01:47:37 PM	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		
Sasha Sims (SSIMS)	Document Control Lead		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tisha Miles (TMILES)	Engr 3, Quality Assurance	09 Dec 2021, 12:04:52 PM	Complete

CR Final Release

Name/Signature	Title	Date	Meaning/Reason
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Jaimie Mowers (JMOWERS)	Sr Quality System Specialist		
Jessica Latimore (JLATIMORE)	Document Control Coordinator		
Rachel Harms (RHARMS)	Documentation Specialist		
Sasha Sims (SSIMS)	Document Control Lead		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tisha Miles (TMILES)	Engr 3, Quality Assurance	09 Dec 2021, 12:05:31 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Rebecca Bigby (10295664)	RA Associate	09 Dec 2021, 12:05:33 PM	Email Sent

Development Released