

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



### DECLARATION OF CONFORMITY

DC Number: DC030061-3

Revision: 5

C. R. Bard, Inc.

located at:  
8195 Industrial Blvd.  
Covington, GA 30014, USA

does hereby declare that the Bard® Catheters Pre-Connected to a Drainage Bag, 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): Class IIb meeting Annex II 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:

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

## DECLARATION OF CONFORMITY

DC Number: DC030061-3

Revision: 5

PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC12582L12	Bardia® all-silicone male length catheter, 12 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12582L14	Bardia® all-silicone male length catheter, 14 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12582L16	Bardia® all-silicone male length catheter, 16 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12582L18	Bardia® all-silicone male length catheter, 18 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12582L20	Bardia® all-silicone male length catheter, 20 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12582L22	Bardia® all-silicone male length catheter, 22 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M12	Bardia® all-silicone male length catheter, 12 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M14	Bardia® all-silicone male length catheter, 14 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M16	Bardia® all-silicone male length catheter, 16 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M18	Bardia® all-silicone male length catheter, 18 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M20	Bardia® all-silicone male length catheter, 20 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12585M22	Bardia® all-silicone male length catheter, 22 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC1258UM12	Bardia® all-silicone male length catheter, 12 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1258UM14	Bardia® all-silicone male length catheter, 14 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC1258UM16	Bardia® all-silicone male length catheter, 16 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1258UM18	Bardia® all-silicone male length catheter, 18 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1258UM20	Bardia® all-silicone male length catheter, 20 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1258UM22	Bardia® all-silicone male length catheter, 22 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC12612L12	Bardia® all-silicone female length catheter, 12 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12612L14	Bardia® all-silicone female length catheter, 14 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12612L16	Bardia® all-silicone female length catheter, 16 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC12615M12	Bardia® all-silicone female length catheter, 12 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12615M14	Bardia® all-silicone female length catheter, 14 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC12615M16	Bardia® all-silicone female length catheter, 16 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC1261UM12	Bardia® all-silicone female length catheter, 12 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1261UM14	Bardia® all-silicone female length catheter, 14 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1261UM16	Bardia® all-silicone female length catheter, 16 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC17582L12	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 12 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17582L14	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 14 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17582L16	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 16 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17582L18	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 18 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17582L20	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 20 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17582L22	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 22 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M12	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 12 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M14	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 14 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M16	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 16 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M18	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 18 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M20	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 20 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17585M22	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 22 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC1758UM12	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 12 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1758UM14	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 14 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1758UM16	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 16 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1758UM18	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 18 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1758UM20	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 20 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1758UM22	Bard® Lubri-Sil® all-silicone hydrogel coated male length catheter, 22 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC17612L12	Bard® Lubri-Si® all-silicone hydrogel coated female length catheter, 12 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17612L14	Bard® Lubri-Si® all-silicone hydrogel coated female length catheter, 14 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17612L16	Bard® Lubri-Si® all-silicone hydrogel coated female length catheter, 16 Fr., pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC17615M12	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 12 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17615M14	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 14 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC17615M16	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 16 Fr., pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC1761UM12	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 12 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1761UM14	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 14 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC1761UM16	Bard® Lubri-Sil® all-silicone hydrogel coated female length catheter, 16 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L12	Bard® Biocath® hydrogel coated male length catheter, 12 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L14	Bard® Biocath® hydrogel coated male length catheter, 14 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L16	Bard® Biocath® hydrogel coated male length catheter, 16 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L18	Bard® Biocath® hydrogel coated male length catheter, 18 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L20	Bard® Biocath® hydrogel coated male length catheter, 20 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22652L22	Bard® Biocath® hydrogel coated male length catheter, 22 Fr., preconnected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M12	Bard® Biocath® hydrogel coated male length catheter, 12 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M14	Bard® Biocath® hydrogel coated male length catheter, 14 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M16	Bard® Biocath® hydrogel coated male length catheter, 16 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M18	Bard® Biocath® hydrogel coated male length catheter, 18 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M20	Bard® Biocath® hydrogel coated male length catheter, 20 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22655M22	Bard® Biocath® hydrogel coated male length catheter, 22 Fr., preconnected to a 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC2265UM12	Bard® Biocath® hydrogel coated male length catheter, 12 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2265UM14	Bard® Biocath® hydrogel coated male length catheter, 14 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2265UM16	Bard® Biocath® hydrogel coated male length catheter, 16 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2265UM18	Bard® Biocath® hydrogel coated male length catheter, 18 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2265UM20	Bard® Biocath® hydrogel coated male length catheter, 20 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2265UM22	Bard® Biocath® hydrogel coated male length catheter, 22 Fr., pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L12	Bard® Biocath® hydrogel coated female length catheter, 12 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L14	Bard® Biocath® hydrogel coated female length catheter, 14 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L16	Bard® Biocath® hydrogel coated female length catheter, 16 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L18	Bard® Biocath® hydrogel coated female length catheter, 18 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L20	Bard® Biocath® hydrogel coated female length catheter, 20 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22692L22	Bard® Biocath® hydrogel coated female length catheter, 22 Fr. pre-connected to a Bardia® 2000ml bedside bag	32031	Urethral catheterization kit, drainage, indwelling
PC22695M12	Bard® Biocath® hydrogel coated female length catheter, 12 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22695M14	Bard® Biocath® hydrogel coated female length catheter, 14 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC22695M16	Bard® Biocath® hydrogel coated female length catheter, 16 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22695M18	Bard® Biocath® hydrogel coated female length catheter, 18 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22695M20	Bard® Biocath® hydrogel coated female length catheter, 20 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC22695M22	Bard® Biocath® hydrogel coated female length catheter, 22 Fr. pre-connected to a Bardia® 500ml short inlet tube leg bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM12	Bard® Biocath® hydrogel coated female length catheter, 12 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM14	Bard® Biocath® hydrogel coated female length catheter, 14 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM16	Bard® Biocath® hydrogel coated female length catheter, 16 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM18	Bard® Biocath® hydrogel coated female length catheter, 18 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM20	Bard® Biocath® hydrogel coated female length catheter, 20 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
PC2269UM22	Bard® Biocath® hydrogel coated female length catheter, 22 Fr. pre-connected to a 350ml center entry urine meter with 2500ml drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165812	Bard® all-silicone male length catheter, 12 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165814	Bard® all-silicone male length catheter, 14 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165816	Bard® all-silicone male length catheter, 16 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165818	Bard® all-silicone male length catheter, 18 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling



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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
SC165820	Bard® all-silicone male length catheter, 20 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165822	Bard® all-silicone male length catheter, 22 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC165824	Bard® all-silicone male length catheter, 24 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SC226512	Bard® Biocath® hydrogel coated catheter, 12 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226514	Bard® Biocath® hydrogel coated catheter, 14 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226516	Bard® Biocath® hydrogel coated catheter, 16 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226518	Bard® Biocath® hydrogel coated catheter, 18 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226520	Bard® Biocath® hydrogel coated catheter, 20 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226522	Bard® Biocath® hydrogel coated catheter, 22 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226524	Bard® Biocath® hydrogel coated catheter, 24 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SC226526	Bard® Biocath® hydrogel coated catheter, 26 Fr., pre-connected to a Uriplan® 2000ml leg bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226512	Bard® Biocath® hydrogel coated male length catheter, 12 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226514	Bard® Biocath® hydrogel coated male length catheter, 14 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226516	Bard® Biocath® hydrogel coated male length catheter, 16 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226518	Bard® Biocath® hydrogel coated male length catheter, 18 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226520	Bard® Biocath® hydrogel coated male length catheter, 20 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
SCC226522	Bard® Biocath® hydrogel coated male length catheter, 22 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling
SCC226524	Bard® Biocath® hydrogel coated male length catheter, 24 Fr., pre-connected to a center entry urine meter with drainage bag	32031	Urethral catheterization kit, drainage, indwelling

Development Released

## DECLARATION OF CONFORMITY

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### REVISION HISTORY

<u>REV. #</u>	<u>CR #</u>	<u>DESCRIPTION</u>
0	TechFile#519	Original. Created Declaration of Conformity to separate Class IIb product codes from Class IIa product codes (DC030061). Product codes SC226308-10 were removed as they are obsolete.
1	TechFile#609	Removed codes 2265125L-165L and 2265125M-165M.
2	BM-COV-CR-01351	Updated document to reflect FM0301166 Rev. 2. Added ® to Bardia, Bard, Lubri-Sil, Biocath, & Uriplan to reflect proper trademarks.
3	BM-COV-CR-20493	Update Notified Body information.
4	BM-COV-CR-07744	Clarified product groups by listing each code separately (PC12582L12-22, PC12585M12-22, PC1258UM12-22, PC12612L12-16, PC12615M12-16, PC1261UM12-16, PC17582L12-22, PC17585M12-22, PC1758UM12-22, PC17612L12-16, PC17615M12-16, PC1761UM12-16, PC22652L12-22, PC22655M12-22, PC2265UM12-22, PC22692L12-22, PC22695M12-22, PC2269UM12-22, SC165812-24, SC226512-26 and SCC226512-24). Updated to reflect FM0301166 Revision 5 which included update to Authorized Representative Information and approval personnel.
5	BM-COV-CR-10105	Updated to reflect FM0301166 Revision 6 which included update to Authorized Representative Information and approval personnel.

## Signature Manifest

**Document Number:** DC030061-3

**Revision:** 5

**Title:** Declaration of Conformity for Technical File 61 for Pre-Connected Catheters

All dates and times are in Eastern Standard Time.

### BM-COV-CR-10105 DoCs updates - TF60, 61, 61-1, 61-2, 61-3 and 63

#### Doc Control Check

Name/Signature	Title	Date	Meaning/Reason
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
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)	Engr 3, Quality Assurance	24 Nov 2021, 01:37:22 PM	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		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tisha Miles (TMILES)	Engr 3, Quality Assurance	24 Nov 2021, 01:37:53 PM	Complete

#### Review/Approve

Name/Signature	Title	Date	Meaning/Reason
Rebecca Bigby (10295664)	RA Associate	02 Dec 2021, 01:53:44 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		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II	07 Dec 2021, 03:25:57 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		
Tisha Miles (TMILES)	Engr 3, Quality Assurance		
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Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II	07 Dec 2021, 03:26:36 PM	Approved

### Notification

Name/Signature	Title	Date	Meaning/Reason
Rebecca Bigby (10295664)	RA Associate	07 Dec 2021, 03:26:38 PM	Email Sent

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