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		
The device catalog number(s) re	eferenced on the attache of 14 June 1993 concern	nected to a Drainage Bag, which consists of d list, meets the provisions and requirements ing medical devices (MDD). The CE marking DD.
Classification (MDD, Annex IX, from Notified Body'	Rule 5): Class IIb meeti	ng Annex II and receipt of CE Certificate
Notified Body:		
BSI Product Services (ID # 279 Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	7)	
C. R. Bard, Inc.'s Authorized Re	presentative is:	
Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland		
Must Meas	19	Nov 2021
VP Quality Assurance, Mark Ne	al Date	
Multill Dans VP Regulatory Affairs, Michele D	Davis Date	Nov 2021

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC12582L12	Bardia® all-silicone male length catheter,	32031	Urethral
	12 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12582L14	Bardia® all-silicone male length catheter,	32031	Urethral
	14 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12582L16	Bardia® all-silicone male length catheter,	32031	Urethral
	16 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12582L18	Bardia® all-silicone male length catheter,	32031	Urethral
	18 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12582L20	Bardia® all-silicone male length catheter,	32031	Urethral
	20 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12582L22	Bardia® all-silicone male length catheter,	32031	Urethral
	22 Fr., pre-connected to a Bardia® 2000ml		catheterization kit,
	bedside bag		drainage, indwelling
PC12585M12	Bardia® all-silicone male length catheter,	32031	Urethral
	12 Fr., pre-connected to a Bardia® 500ml		catheterization kit,
DOJOEOGNAJA	short inlet tube leg bag	20024	drainage, indwelling
PC12585M14	Bardia® all-silicone male length catheter,	32031	Urethral
	14 Fr., pre-connected to a Bardia® 500ml		catheterization kit,
DO40F0FM4C	short inlet tube leg bag	22024	drainage, indwelling
PC12585M16	Bardia® all-silicone male length catheter,	32031	Urethral
	16 Fr., pre-connected to a Bardia® 500ml		catheterization kit,
PC12585M18	short inlet tube leg bag	32031	drainage, indwelling Urethral
PC12303W110	Bardia® all-silicone male length catheter, 18 Fr., pre-connected to a Bardia® 500ml	32031	catheterization kit,
	short inlet tube leg bag		drainage, indwelling
PC12585M20	Bardia® all-silicone male length catheter,	32031	Urethral
FG123031V120	20 Fr., pre-connected to a Bardia® 500ml	32031	catheterization kit,
	short inlet tube leg bag		drainage, indwelling
PC12585M22	Bardia® all-silicone male length catheter,	32031	Urethral
1 0 12000IVIZZ	22 Fr., pre-connected to a Bardia® 500ml	02001	catheterization kit,
	short inlet tube leg bag		drainage, indwelling
PC1258UM12	Bardia® all-silicone male length catheter,	32031	Urethral
. 0.20002	12 Fr., pre-connected to a 350ml center	0200.	catheterization kit,
	entry urine meter with 2500ml drainage		drainage, indwelling
	bag		
PC1258UM14	Bardia® all-silicone male length catheter,	32031	Urethral
	14 Fr., pre-connected to a 350ml center		catheterization kit,
	entry urine meter with 2500ml drainage		drainage, indwelling
	bag		

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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., preconnected 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., preconnected 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., preconnected 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., preconnected 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., preconnected 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., preconnected 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., preconnected 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., preconnected 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., preconnected 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	32031	Urethral
	coated male length catheter, 12 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC1758UM14	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated male length catheter, 14 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC1758UM16	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated male length catheter, 16 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC1758UM18	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated male length catheter, 18 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC1758UM20	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated male length catheter, 20 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC1758UM22	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated male length catheter, 22 Fr., pre-		catheterization kit,
	connected to a 350ml center entry urine		drainage, indwelling
	meter with 2500ml drainage bag		
PC17612L12	Bard® Lubri-Si®l all-silicone hydrogel	32031	Urethral
	coated female length catheter, 12 Fr., pre-		catheterization kit,
	connected to a Bardia® 2000ml bedside		drainage, indwelling
	bag		3
PC17612L14	Bard® Lubri-Si®l all-silicone hydrogel	32031	Urethral
	coated female length catheter, 14 Fr., pre-	====	catheterization kit,
	connected to a Bardia® 2000ml bedside		drainage, indwelling
	bag		aramago, aramamig
PC17612L16	Bard® Lubri-Si®l all-silicone hydrogel	32031	Urethral
	coated female length catheter, 16 Fr., pre-	====	catheterization kit,
	connected to a Bardia® 2000ml bedside		drainage, indwelling
	bag		
PC17615M12	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
	coated female length catheter, 12 Fr., pre-	====	catheterization kit,
	connected to a Bardia® 500ml short inlet		drainage, indwelling
	tube leg bag		aramage, marrening
PC17615M14	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
. 31.0101111	coated female length catheter, 14 Fr., pre-	0230.	catheterization kit,
	connected to a Bardia® 500ml short inlet		drainage, indwelling
	tube leg bag		aramago, mawoning
PC17615M16	Bard® Lubri-Sil® all-silicone hydrogel	32031	Urethral
1 317 0 10 101 10	coated female length catheter, 16 Fr., pre-	02001	catheterization kit,
	connected to a Bardia® 500ml short inlet		drainage, indwelling
	tube leg bag		drainage, indweiling
	l rane led had	1	

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

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC2265UM12	Bard® Biocath® hydrogel coated male	32031	Urethral
	length catheter, 12 Fr., pre-connected to a		catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		
PC2265UM14	Bard® Biocath® hydrogel coated male	32031	Urethral
	length catheter, 14 Fr., pre-connected to a		catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
DCOOCELIMAC	2500ml drainage bag	22024	Lingthrol
PC2265UM16	Bard® Biocath® hydrogel coated male	32031	Urethral
	length catheter, 16 Fr., pre-connected to a		catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
PC2265UM18	2500ml drainage bag Bard® Biocath® hydrogel coated male	32031	Urethral
F G Z Z G G G W I T G	length catheter, 18 Fr., pre-connected to a	32031	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		drainage, indwelling
PC2265UM20	Bard® Biocath® hydrogel coated male	32031	Urethral
1 02200011120	length catheter, 20 Fr., pre-connected to a	02001	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		3-,
PC2265UM22	Bard® Biocath® hydrogel coated male	32031	Urethral
	length catheter, 22 Fr., pre-connected to a		catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		
PC22692L12	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 12 Fr. pre-connected to a		catheterization kit,
	Bardia® 2000ml bedside bag		drainage, indwelling
PC22692L14	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 14 Fr. pre-connected to a		catheterization kit,
	Bardia® 2000ml bedside bag		drainage, indwelling
PC22692L16	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 16 Fr. pre-connected to a		catheterization kit,
	Bardia® 2000ml bedside bag		drainage, indwelling
PC22692L18	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 18 Fr. pre-connected to a		catheterization kit,
DOCCOCCI CO	Bardia® 2000ml bedside bag	22224	drainage, indwelling
PC22692L20	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 20 Fr. pre-connected to a		catheterization kit,
D0000001.00	Bardia® 2000ml bedside bag	20024	drainage, indwelling
PC22692L22	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 22 Fr. pre-connected to a		catheterization kit,
DC22605M42	Bardia® 2000ml bedside bag Bard® Biocath® hydrogel coated female	22024	drainage, indwelling Urethral
PC22695M12	length catheter, 12 Fr. pre-connected to a	32031	catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
PC22695M14	Bard® Biocath® hydrogel coated female	32031	Urethral
1 0220301VI 14	length catheter, 14 Fr. pre-connected to a	32031	catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
	Dardia Journi Short lillet tube leg bag		Taramaye, muweming

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
PC22695M16	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 16 Fr. pre-connected to a		catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
PC22695M18	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 18 Fr. pre-connected to a		catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
PC22695M20	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 20 Fr. pre-connected to a		catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
PC22695M22	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 22 Fr. pre-connected to a		catheterization kit,
	Bardia® 500ml short inlet tube leg bag		drainage, indwelling
PC2269UM12	Bard® Biocath® hydrogel coated female	32031	Urethral
	length catheter, 12 Fr. pre-connected to a		catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		a.ag
PC2269UM14	Bard® Biocath® hydrogel coated female	32031	Urethral
. 022000	length catheter, 14 Fr. pre-connected to a	0200.	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		dramago, mawoming
PC2269UM16	Bard® Biocath® hydrogel coated female	32031	Urethral
1 02203011110	length catheter, 16 Fr. pre-connected to a	02001	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		drainage, indivening
PC2269UM18	Bard® Biocath® hydrogel coated female	32031	Urethral
1 02203011110	length catheter, 18 Fr. pre-connected to a	02001	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		drainage, indwelling
PC2269UM20	Bard® Biocath® hydrogel coated female	32031	Urethral
1 02203010120	length catheter, 20 Fr. pre-connected to a	32031	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		drainage, indwelling
PC2269UM22	Bard® Biocath® hydrogel coated female	32031	Urethral
1 OZZOSOWIZZ	length catheter, 22 Fr. pre-connected to a	02001	catheterization kit,
	350ml center entry urine meter with		drainage, indwelling
	2500ml drainage bag		drainage, indwelling
SC165812	Bard® all-silicone male length catheter, 12	32031	Urethral
00100012	Fr., pre-connected to a center entry urine	32001	catheterization kit,
	meter with drainage bag		drainage, indwelling
SC165814	Bard® all-silicone male length catheter, 14	32031	Urethral
00100014	Fr., pre-connected to a center entry urine	02001	catheterization kit,
	meter with drainage bag		drainage, indwelling
SC165816	Bard® all-silicone male length catheter, 16	32031	Urethral
00100010	Fr., pre-connected to a center entry urine	02001	catheterization kit,
	meter with drainage bag		drainage, indwelling
SC165818	Bard® all-silicone male length catheter, 18	32031	Urethral
30 100010		32031	catheterization kit,
	Fr., pre-connected to a center entry urine		*
	meter with drainage bag	j	drainage, indwelling

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PRODUCT CODE	PRODUCT DESCRIPTION	GMDN Code	GMDN Term
SC165820	Bard® all-silicone male length catheter, 20	32031	Urethral
	Fr., pre-connected to a center entry urine		catheterization kit,
	meter with drainage bag		drainage, indwelling
SC165822	Bard® all-silicone male length catheter, 22	32031	Urethral
	Fr., pre-connected to a center entry urine		catheterization kit,
	meter with drainage bag		drainage, indwelling
SC165824	Bard® all-silicone male length catheter, 24	32031	Urethral
	Fr., pre-connected to a center entry urine		catheterization kit,
	meter with drainage bag		drainage, indwelling
SC226512	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
	12 Fr., pre-connected to a Uriplan®		catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226514	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
	14 Fr., pre-connected to a Uriplan®		catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226516	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
	16 Fr., pre-connected to a Uriplan®		catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226518	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
	18 Fr., pre-connected to a Uriplan®		catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226520	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
0000_0	20 Fr., pre-connected to a Uriplan®	0_00.	catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226522	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
00220022	22 Fr., pre-connected to a Uriplan®	0200.	catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226524	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
	24 Fr., pre-connected to a Uriplan®	0_00.	catheterization kit,
	2000ml leg bag		drainage, indwelling
SC226526	Bard® Biocath® hydrogel coated catheter,	32031	Urethral
00220020	26 Fr., pre-connected to a Uriplan®	02001	catheterization kit,
	2000ml leg bag		drainage, indwelling
SCC226512	Bard® Biocath® hydrogel coated male	32031	Urethral
000220012	length catheter, 12 Fr., pre-connected to a	02001	catheterization kit,
	center entry urine meter with drainage bag		drainage, indwelling
SCC226514	Bard® Biocath® hydrogel coated male	32031	Urethral
000220014	length catheter, 14 Fr., pre-connected to a	02001	catheterization kit,
	center entry urine meter with drainage bag		drainage, indwelling
SCC226516	Bard® Biocath® hydrogel coated male	32031	Urethral
000220010	length catheter, 16 Fr., pre-connected to a	02001	catheterization kit,
	center entry urine meter with drainage bag		drainage, indwelling
SCC226518	Bard® Biocath® hydrogel coated male	32031	Urethral
000220010	length catheter, 18 Fr., pre-connected to a	02001	catheterization kit,
	center entry urine meter with drainage bag		drainage, indwelling
SCC226520	Bard® Biocath® hydrogel coated male	32031	Urethral
000220020	length catheter, 20 Fr., pre-connected to a	32031	catheterization kit,
	1		
	center entry urine meter with drainage bag		drainage, indwelling

DC Number: DC030061-3 Revision: 5

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

DC Number: DC030061-3 Revision: 5

REVISION HISTORY

REV. # 0	CR # TechFile#519	DESCRIPTION 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		
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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		
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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		
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Tyrone Jackson (TJACKSON)	Document Contrl. Coord. II	07 Dec 2021, 03:25:57 PM	Complete

CR Final Release

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Bexaida Rivera (BRIVERA)	Doc. Control Coord. II		
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