

Bard Peripheral Vascular, Inc.
C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
Tel: (800) 321-4254
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DOC BBS002 Rev. 4



DECLARATION OF CONFORMITY Medical Devices

Manufacturer: Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

The manufacturer (Bard Peripheral Vascular, Inc.) is exclusively responsible for this Declaration of Conformity.

Product Family: Bard[®] Mission[®] Disposable Core Biopsy Instruments and Kits
Bard[®] MaxCore[®] Disposable Core Biopsy Instruments
Bard[®] Monopty[®] Disposable Core Biopsy Instruments
Bard[®] Marquee[®] Disposable Core Biopsy Instruments and Kits

Product Classification: Class IIa

Classification Rule: Medical Device Directive 93/42/EEC, Annex IX, Rule 6 and 9


The undersigned hereby declares that the medical device(s) specified in Appendix A conform to the Essential Requirements listed in Annex I of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC. The conformity assessment complies with Annex II (excluding Section 4) of the Medical Device Directive 93/42/EEC as amended 2007/47/EC.

This declaration is supported by:

- EC quality system approval statement, Medical Device Directive 93/42/EEC, Annex II, Section 3.2

Certificate No.	:	CE No. 01467
Issued By	:	British Standards Institution
Notified Body No.	:	2797
EU Authorized Representative	:	BD Switzerland Sàrl Terre Bonne Park – A4 Route de Crassier 17 1262 Eysins – Switzerland

19 Jul 2017
Date


Sarah McCartney
Sr. Project Manager, Regulatory Affairs

**APPENDIX A****PRODUCT MATRIX**

This Declaration of Conformity covers Bard® Mission® Disposable Core Biopsy Instruments and Kits, Bard® MaxCore® Disposable Core Biopsy Instruments, Bard® Monopty® Disposable Core Biopsy Instruments and Bard® Marquee® Disposable Core Biopsy Instruments of the following item numbers:

Bard® Mission® Disposable Core Biopsy Instruments and Kits

Item Number	Product Name	Dimensions
1406MS	Bard® Mission® Disposable Core Biopsy Instrument	14g x 6 cm
1410MS	Bard® Mission® Disposable Core Biopsy Instrument	14g x 10 cm
1416MS	Bard® Mission® Disposable Core Biopsy Instrument	14g x 16 cm
1606MS	Bard® Mission® Disposable Core Biopsy Instrument	16g x 6 cm
1610MS	Bard® Mission® Disposable Core Biopsy Instrument	16g x10 cm
1616MS	Bard® Mission® Disposable Core Biopsy Instrument	16g x 16 cm
1806MS	Bard® Mission® Disposable Core Biopsy Instrument	18g x 6 cm
1810MS	Bard® Mission® Disposable Core Biopsy Instrument	18g x10 cm
1816MS	Bard® Mission® Disposable Core Biopsy Instrument	18g x16 cm
1820MS	Bard® Mission® Disposable Core Biopsy Instrument	18g x 20 cm
1825MS	Bard® Mission® Disposable Core Biopsy Instrument	18g x 25 cm
2006MS	Bard® Mission® Disposable Core Biopsy Instrument	20g x 6 cm
2010MS	Bard® Mission® Disposable Core Biopsy Instrument	20g x10 cm
2016MS	Bard® Mission® Disposable Core Biopsy Instrument	20g x 16 cm
2020MS	Bard® Mission® Disposable Core Biopsy Instrument	20g x 20 cm
1410MSK	Bard® Mission® Disposable Core Biopsy Kit	14g x 10 cm
1416MSK	Bard® Mission® Disposable Core Biopsy Kit	14g x 16 cm
1610MSK	Bard® Mission® Disposable Core Biopsy Kit	16g x 10 cm
1616MSK	Bard® Mission® Disposable Core Biopsy Kit	16g x 16 cm
1810MSK	Bard® Mission® Disposable Core Biopsy Kit	18g x 10 cm
1816MSK	Bard® Mission® Disposable Core Biopsy Kit	18g x 16 cm
1820MSK	Bard® Mission® Disposable Core Biopsy Kit	18g x 20 cm
1825MSK	Bard® Mission® Disposable Core Biopsy Kit	18g x 25 cm
2010MSK	Bard® Mission® Disposable Core Biopsy Kit	20g x 10 cm
2016MSK	Bard® Mission® Disposable Core Biopsy Kit	20g x 16 cm
2020MSK	Bard® Mission® Disposable Core Biopsy Kit	20g x 20 cm



Bard® MaxCore® Disposable Core Biopsy Instruments

Item Number	Product Name	Dimensions
MC1410	Bard® MaxCore® Disposable Core Biopsy Instrument	14g x 10 cm
MC1416	Bard® MaxCore® Disposable Core Biopsy Instrument	14g x 16 cm
MC1610	Bard® MaxCore® Disposable Core Biopsy Instrument	16g x 10 cm
MC1616	Bard® MaxCore® Disposable Core Biopsy Instrument	16g x 16 cm
MC1810	Bard® MaxCore® Disposable Core Biopsy Instrument	18g x 10 cm
MC1816	Bard® MaxCore® Disposable Core Biopsy Instrument	18g x 16 cm
MC1820	Bard® MaxCore® Disposable Core Biopsy Instrument	18g x 20 cm
MC1825	Bard® MaxCore® Disposable Core Biopsy Instrument	18g x 25 cm
MC2010	Bard® MaxCore® Disposable Core Biopsy Instrument	20g x 10 cm
MC2016	Bard® MaxCore® Disposable Core Biopsy Instrument	20g x 16 cm
MC2020	Bard® MaxCore® Disposable Core Biopsy Instrument	20g x 20 cm

Bard® Monopty® Disposable Core Biopsy Instruments

Item Number	Product Name	Dimensions
22mm Penetration Depth		
121210	Bard® Monopty® Disposable Core Biopsy Instrument	12g x 10 cm
121216	Bard® Monopty® Disposable Core Biopsy Instrument	12g x 16 cm
121410	Bard® Monopty® Disposable Core Biopsy Instrument	14g x 10 cm
121416	Bard® Monopty® Disposable Core Biopsy Instrument	14g x 16 cm
121610	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 10 cm
121616	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 16 cm
121620	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 20 cm
121810	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 10 cm
121816	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 16 cm
121820	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 20 cm
122010	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 10 cm
122016	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 16 cm
122020	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 20 cm
11mm Penetration Depth		
211410	Bard® Monopty® Disposable Core Biopsy Instrument	14g x 9 cm
211416	Bard® Monopty® Disposable Core Biopsy Instrument	14g x 15 cm
211610	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 9 cm
211616	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 15 cm
211620	Bard® Monopty® Disposable Core Biopsy Instrument	16g x 19 cm
211810	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 9 cm
211816	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 15 cm
211820	Bard® Monopty® Disposable Core Biopsy Instrument	18g x 19 cm
212010	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 9 cm
212016	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 15 cm
212020	Bard® Monopty® Disposable Core Biopsy Instrument	20g x 19 cm

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Bard® Marquee® Disposable Core Biopsy Instruments and Kits

Item Number	Product Name	Dimensions
MQ1210	Bard® Marquee® Disposable Core Biopsy Instrument	12g x 10cm
MQ1213	Bard® Marquee® Disposable Core Biopsy Instrument	12g x 13cm
MQ1410	Bard® Marquee® Disposable Core Biopsy Instrument	14g x 10cm
MQ1413	Bard® Marquee® Disposable Core Biopsy Instrument	14g x 13cm
MQ1416	Bard® Marquee® Disposable Core Biopsy Instrument	14g x 16cm
MQ1610	Bard® Marquee® Disposable Core Biopsy Instrument	16g x 10cm
MQ1616	Bard® Marquee® Disposable Core Biopsy Instrument	16g x 16cm
MQ1620	Bard® Marquee® Disposable Core Biopsy Instrument	16g x 20cm
MQ1810	Bard® Marquee® Disposable Core Biopsy Instrument	18g x 10cm
MQ1816	Bard® Marquee® Disposable Core Biopsy Instrument	18g x 16cm
MQ1820	Bard® Marquee® Disposable Core Biopsy Instrument	18g x 20cm
MQ1825	Bard® Marquee® Disposable Core Biopsy Instrument	18g x 25cm
MQ2010	Bard® Marquee® Disposable Core Biopsy Instrument	20g x 10cm
MQ2016	Bard® Marquee® Disposable Core Biopsy Instrument	20g x 16cm
MQ2020	Bard® Marquee® Disposable Core Biopsy Instrument	20g x 20cm
MQK1210	Bard® Marquee® Disposable Core Biopsy Instrument Kit	12g x 10cm
MQK1213	Bard® Marquee® Disposable Core Biopsy Instrument Kit	12g x 13cm
MQK1410	Bard® Marquee® Disposable Core Biopsy Instrument Kit	14g x 10cm
MQK1413	Bard® Marquee® Disposable Core Biopsy Instrument Kit	14g x 13cm
MQK1416	Bard® Marquee® Disposable Core Biopsy Instrument Kit	14g x 16cm
MQK1610	Bard® Marquee® Disposable Core Biopsy Instrument Kit	16g x 10cm
MQK1616	Bard® Marquee® Disposable Core Biopsy Instrument Kit	16g x 16cm
MQK1620	Bard® Marquee® Disposable Core Biopsy Instrument Kit	16g x 20cm
MQK1810	Bard® Marquee® Disposable Core Biopsy Instrument Kit	18g x 10cm
MQK1816	Bard® Marquee® Disposable Core Biopsy Instrument Kit	18g x 16cm
MQK1820	Bard® Marquee® Disposable Core Biopsy Instrument Kit	18g x 20cm
MQK1825	Bard® Marquee® Disposable Core Biopsy Instrument Kit	18g x 25cm
MQK2010	Bard® Marquee® Disposable Core Biopsy Instrument Kit	20g x 10cm
MQK2016	Bard® Marquee® Disposable Core Biopsy Instrument Kit	20g x 16cm
MQK2020	Bard® Marquee® Disposable Core Biopsy Instrument Kit	20g x 20cm



HISTORY OF DECLARATION OF CONFORMITY FOR

Product Family:

Bard[®] Mission[®] Disposable Core Biopsy Instruments and Kits
Bard[®] MaxCore[®] Disposable Core Biopsy Instruments
Bard[®] Monopty[®] Disposable Core Biopsy Instruments
Bard[®] Marquee[®] Disposable Core Biopsy Instruments and Kits

Revision	Date	Description of Change
0	21 Feb 2017	Introduction of Revision Control as per SOPR0700140 Rev. 18. Revised Declaration of Conformity in accordance with MDD 93/42/EEC as amended by 2007/47/EC.
1	27 March 2018	Added Mission product codes for the launch of the 6cm Mission Line Extension and updated minor formatting.
2	29 June 2018	Added Mission product codes for the launch of the full Mission Line Extension.
3	12 March 2019	Update to new Notified Body Number and EU Authorized Representative address.
4	19 July 2019	Retrospectively updated Mission product code table to reflect Revision 2.