



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® Coaxial Biopsy Needles
Bard® TruGuide Disposable Coaxial Biopsy Needles**

Product Classification: **Class IIa**

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

The undersigned hereby declares that the medical device(s) specified in the 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.

Product Family: **Bard® Needle Guide for use with Lorad Stereotactic System**

Product Classification: **Class I**

Classification Rule: **Medical Device Directive 93/42/EEC, Annex IX, Rule 1**

The undersigned hereby declares that the medical device(s) specified in the 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 sections 4 and 8) and Annex VII (excluding section 6) 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**

Bard Peripheral Vascular, Inc.

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EU Authorized Representative

:

Becton Dickinson Ireland Limited
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DocuSigned by:

Jennifer Logvin



Signer Name: Jennifer Logvin
Signing Reason: I approve this document
Signing Time: 24-Jun-2022 | 7:31:03 PM EDT

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Date

Jennifer Logvin
Vice President, Regulatory Affairs

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

This Declaration of Conformity covers Bard® Coaxial Biopsy Needles, Bard® TruGuide Disposable Coaxial Biopsy Needles, and Bard® Needle Guide for use with the Lorad Stereotactic System of the following item numbers:

Bard® Coaxial Biopsy Needles

Item Number	Product Name	Dimensions
AX1410	Bard® Coaxial Biopsy Needle	13g x 7 cm
AX1413	Bard® Coaxial Biopsy Needle	13g x 10 cm
AX1416	Bard® Coaxial Biopsy Needle	13g x 13 cm

Bard® TruGuide Disposable Coaxial Biopsy Needles

Item Number	Product Name	Dimensions
C1210A	Bard® TruGuide Disposable Coaxial Biopsy Needles	11g x 7.8cm
C1216A	Bard® TruGuide Disposable Coaxial Biopsy Needles	11g x 13.8cm
C1410A	Bard® TruGuide Disposable Coaxial Biopsy Needles	13g x 7.8cm
C1416A	Bard® TruGuide Disposable Coaxial Biopsy Needles	13g x 13.8cm
C1610A	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 7.8cm
C1616A	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 13.8cm
C1620A	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 17.8cm
C1810A	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 7.8cm
C1816A	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 13.8cm
C1820A	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 17.8cm
C2010A	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 7.8cm
C2016A	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 13.8cm
C2020A	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 17.8cm
C1210B	Bard® TruGuide Disposable Coaxial Biopsy Needles	11g x 7cm
C1213B	Bard® TruGuide Disposable Coaxial Biopsy Needles	11g x 10cm
C1216B	Bard® TruGuide Disposable Coaxial Biopsy Needles	11g x 13cm
C1410B	Bard® TruGuide Disposable Coaxial Biopsy Needles	13g x 7cm
C1413B	Bard® TruGuide Disposable Coaxial Biopsy Needles	13g x 10cm
C1416B	Bard® TruGuide Disposable Coaxial Biopsy Needles	13g x 13cm
C1610B	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 7cm
C1613B	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 10cm
C1616B	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 13cm
C1620B	Bard® TruGuide Disposable Coaxial Biopsy Needles	15g x 17cm
C1810B	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 7cm

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Item Number	Product Name	Dimensions
C1813B	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 10cm
C1816B	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 13cm
C1820B	Bard® TruGuide Disposable Coaxial Biopsy Needles	17g x 17cm
C2010B	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 7cm
C2013B	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 10cm
C2016B	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 13cm
C2020B	Bard® TruGuide Disposable Coaxial Biopsy Needles	19g x 17cm

Bard® Needle Guide for use with Lorad Stereotactic System

Item Number	Product Name	Dimensions
GL1200	Bard® Lorad Needle Guides	Fits 12g Needle
GL1416	Bard® Lorad Needle Guides	Fits 14g or 16g Needle
GL1820	Bard® Lorad Needle Guides	Fits 18g or 20g Needle



HISTORY OF DECLARATION OF CONFORMITY FOR

Product Family: **Bard® Coaxial Biopsy Needles**
Bard® TruGuide Disposable Coaxial Biopsy Needles
Bard® Needle Guide for use with Lorad Stereotactic
System

Revision	Date	Description of Change
0	20 Jan 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	12 March 2019	Update to new Notified Body Number and EU Authorized Representative address.
2	23 June 2022	Update to Authorized Representative address to reflect change to Becton Dickinson Ireland Limited.