

**BD Peripheral Intervention**

1625 West 3<sup>rd</sup> Street  
Tempe, AZ 85281  
Tel: (800) 321-4254  
(480) 894-9515  
Fax: (480) 966-7062



DOC BBS0021



## **DECLARATION OF CONFORMITY**

### **Medical Devices**

*Manufacturer:* **Bard Peripheral Vascular, Inc.**  
**1625 West 3<sup>rd</sup> Street**  
**Tempe, AZ 85281**  
**USA**

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

*Product Family:* **BD EleVation™ Breast Biopsy System**

*Product Classification:* **Class IIa**

*Classification Rule:* **Medical Device Directive 93/42/EEC, Annex II, Rule 6 and 11**

The undersigned hereby declares that the medical device(s) specified in Appendix A comply with Annex II of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), as amended.

Additionally, the Item Numbers specified in Appendix A, have met the requirements of Commission Delegated Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council.

*This declaration is supported by:*

Certificate No.	:	<b>CE No. 01467</b>
Issued By	:	<b>British Standards Institution</b>
Notified Body No.	:	<b>2797</b>
EU Authorized Representative	:	<b>BD Switzerland Sàrl</b> <b>Terre Bonne Park – A4</b> <b>Route de Crassier 17</b> <b>1262 Eysins – Switzerland</b> <b>Tel: +41 (0) 21 556 30 00</b>

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Issued at, and under the sole responsibility of,  
Bard Peripheral Vascular, Inc.  
Tempe, Arizona on January 15, 2021

*Joni Anderson*

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Joni Anderson  
Vice President of Regulatory Affairs

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**APPENDIX A****BD EleVation™ Breast Biopsy System  
Class IIa**

End Item Product Code	Product Description
EV10	BD EleVation™ Breast Biopsy Probe 10G
EV12	BD EleVation™ Breast Biopsy Probe 12G
EV14	BD EleVation™ Breast Biopsy Probe 14G
EVDriver	BD EleVation™ Breast Biopsy Driver
EVSC	BD EleVation™ Breast Biopsy Sample Containers
EVH10	BD EleVation™ Breast Biopsy Half-Notch Support Cannula 10G
EVH12	BD EleVation™ Breast Biopsy Half-Notch Support Cannula 12G
EVH14	BD EleVation™ Breast Biopsy Half-Notch Support Cannula 14G
EV10S	BD EleVation™ Breast Biopsy Introducer Stylet 10G
EV12S	BD EleVation™ Breast Biopsy Introducer Stylet 12G
EV14S	BD EleVation™ Breast Biopsy Introducer Stylet 14G