



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA		
Manufacturer SRN:	US-MF-000018910		
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland		
Authorised Representative SRN:	IE-AR-000007610		
Product:	Catalog Number	Product Trade Name	
	441749	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q ^x Amplified DNA Assays Reagent Pack	
	441128	BD Viper™ Extraction Reagent and Lysis Trough	
	441853	BD Viper™ System Accessories	
	440984	BD Viper™ Amplification Plate Sealers (Black)	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	441749	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q ^x Amplified DNA Assays Reagent Pack	038290GHBIGOBKYZ
	441128	BD Viper™ Extraction Reagent and Lysis Trough	038290UQBIEDWWER
	441853	BD Viper™ System Accessories	038290CJLJZHLT8R
	440984	BD Viper™ Amplification Plate Sealers (Black)	038290TEWUBPJJKM
Risk Class and Rule :	Catalog Number	Product Trade Name	Risk Class and Rule
	441749	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q ^x Amplified DNA Assays Reagent Pack	Class C, Rule 3(a)
	441128	BD Viper™ Extraction Reagent and Lysis Trough	Class A, Rule 5(a)



	<table><tr><td>441853</td><td>BD Viper™ System Accessories</td><td>Class A, Rule 5(a)</td></tr><tr><td>440984</td><td>BD Viper™ Amplification Plate Sealers (Black)</td><td>Class A, Rule 5(a)</td></tr></table>	441853	BD Viper™ System Accessories	Class A, Rule 5(a)	440984	BD Viper™ Amplification Plate Sealers (Black)	Class A, Rule 5(a)						
441853	BD Viper™ System Accessories	Class A, Rule 5(a)											
440984	BD Viper™ Amplification Plate Sealers (Black)	Class A, Rule 5(a)											
Intended Purpose:	<table><tr><th>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr><tr><td>441749</td><td>BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays Reagent Pack</td><td rowspan="4">The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q^x Amplified DNA Assays (HSV Q^x Assays) are automated assays, when tested with the BD Viper™ System in Extracted Mode, use Strand Displacement Amplification technology for the direct, qualitative detection and differentiation of Herpes Simplex virus type 1 (HSV1) and Herpes Simplex virus type 2 (HSV2) DNA in clinician-collected external anogenital lesion specimens. The assays are indicated for use with symptomatic individuals to aid in the diagnosis of anogenital HSV1 and HSV2 infections.</td></tr><tr><td>441128</td><td>BD Viper™ Extraction Reagent and Lysis Trough</td></tr><tr><td>441853</td><td>BD Viper™ System Accessories</td></tr><tr><td>440984</td><td>BD Viper™ Amplification Plate Sealers (Black)</td></tr></table>	Catalog Number	Product Trade Name	Intended Purpose	441749	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q ^x Amplified DNA Assays Reagent Pack	The BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q ^x Amplified DNA Assays (HSV Q ^x Assays) are automated assays, when tested with the BD Viper™ System in Extracted Mode, use Strand Displacement Amplification technology for the direct, qualitative detection and differentiation of Herpes Simplex virus type 1 (HSV1) and Herpes Simplex virus type 2 (HSV2) DNA in clinician-collected external anogenital lesion specimens. The assays are indicated for use with symptomatic individuals to aid in the diagnosis of anogenital HSV1 and HSV2 infections.	441128	BD Viper™ Extraction Reagent and Lysis Trough	441853	BD Viper™ System Accessories	440984	BD Viper™ Amplification Plate Sealers (Black)
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Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797												
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s): <ul style="list-style-type: none">Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.													

**Conformity Assessment Route:**

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: 750848 EC Certificate Expiration Date: 2027-05-22
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
441749	BD ProbeTec™ Herpes Simplex Viruses (HSV 1 & 2) Q* Amplified DNA Assays Reagent Pack	Class C
441128	BD Viper™ Extraction Reagent and Lysis Trough	Class A*
441853	BD Viper™ System Accessories	Class A*
440984	BD Viper™ Amplification Plate Sealers (Black)	Class A*

*Class A non-sterile products are self-certified and therefore not reviewed by the Notified Body.

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	<div><div>DocuSigned by:</div><div>Anne Zavertnik</div><div><div></div><div>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:36:47 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial Release
02	Removed controls (441748) as not declaring IVDR compliance at this time.
03	Converted to new template CBI-058 FRM24 (IVDR DoC) Revision 04 Updated “On behalf of” with Legal Manufacturer’s name. Removed “Not available” from Common Specifications (CS) table. Minor formatting changes.