

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
Manufacturer SRN:	CH-MF-000026539
Authorised Representative:	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	BD PhaSeal™ Optima Injector BD PhaSeal™ Optima Protector BD PhaSeal™ Optima Connector BD PhaSeal™ Optima Infusion Adapter BD PhaSeal™ Protector BD PhaSeal™ Injector Luer Lock BD PhaSeal™ Connector Luer Lock BD PhaSeal™ Infusion Adapter BD PhaSeal™ Secondary & Infusion Set BD PhaSeal™ Connector
Basic UDI-DI:	038290GXTCIFNIEV 038290HESACSUA56 038290DUOGE BDB7Y 038290TEQZHTFILE 038290WIPAD XWZHQ 038290OFLSDDBOA6 038290TJWYTEAXRW 038290KWGIRIZDGR 038290BZTLBYHQHF 038290TLMOSQKALM
Risk Class and Rule:	Class IIa, Annex VIII, Rule 2 Class IIa, Annex VIII, Rule 12

Intended Purpose

The BD PhaSeal™ Optima Protector is a drug vial adapter intended for closed preparation and reconstitution of hazardous parenteral drugs when used with a BD PhaSeal™ Optima Injector.

The BD PhaSeal™ Optima Injector has a female Luer Lock that mates with a male Luer Lock (e.g., syringe, IV line) intended for the closed preparation and administration of hazardous parenteral drugs when used with BD PhaSeal™ Optima System devices.

The BD PhaSeal™ Optima Connector has a male Luer Lock that mates with a female Luer Lock intended for the closed preparation and administration of hazardous parenteral drugs when used with a BD PhaSeal™ Optima Injector.

The BD PhaSeal™ Optima Infusion Adapter is an IV container spike that attaches to an IV line and is intended for the closed preparation and/or administration of hazardous parenteral drugs when used with a BD PhaSeal™ Optima Injector.

The BD PhaSeal™ Protector is a drug vial adapter intended for closed preparation and reconstitution of non-hazardous or hazardous parenteral drugs when used with a BD PhaSeal™ Injector.

The BD PhaSeal™ Injector Luer has a female luer lock that mates with a male luer lock (e.g., syringe, IV line) intended for the closed preparation and administration of non-hazardous or hazardous parenteral drugs when used with BD PhaSeal™ System devices.

The BD PhaSeal™ Connector has a male luer lock that mates with a female luer lock intended for the closed preparation and administration of non-hazardous or hazardous parenteral drugs when used with a BD PhaSeal™ Injector.

The BD PhaSeal™ Infusion Adapter is an IV container spike that attaches to an IV line and is intended for the preparation and/or administration of non-hazardous or hazardous parenteral drugs when used with a BD PhaSeal™ Injector.

The BD PhaSeal™ Infusion Set is intended for the closed preparation and administration of non-hazardous or hazardous parenteral drugs from an intravenous (IV) container to a patient's vascular system when used with a BD PhaSeal™ Injector.

The BD PhaSeal™ Secondary Set is intended for the closed preparation and administration of non-hazardous or hazardous parenteral drugs from an Intravenous (IV) container to a patient's vascular system. The BD PhaSeal™ Secondary Set attaches to a primary administration set when used with a BD PhaSeal™ Injector.

The BD PhaSeal™ L Connector, when used with a BD PhaSeal™ Injector, is intended to be connected to an IV container via a spike for the closed preparation of non-hazardous or hazardous parenteral drugs.



	The BD PhaSeal™ Y-site Connector, when used with a BD PhaSeal™ Injector, is intended for the closed administration of non-hazardous or hazardous parenteral drugs as an extension line to the patient's vascular system.
Notified Body:	BSI 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) 2017/745 of the European Parliament and of the Council on Medical Devices	

Conformity Assessment Route:

<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.:MDR 745680 Certificate Expiration Date: 2028-09-03
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Common Specifications (CS):


Number:	Title:	Full or Partial Application:
Common Specifications have not been issued for this product.		

Devices Covered by this DoC:

SKU#	Device Name	Device Class
515052	BD PhaSeal™ Optima Injector (N35-O)	IIa
515053	BD PhaSeal™ Optima Injector (N35-O Multi)	IIa
515056	BD PhaSeal™ Optima Injector N40-O	IIa
515057	BD PhaSeal™ Optima Injector (N40-O Multi)	IIa
515060	BD PhaSeal™ Optima Protector (P13-O)	IIa
515062	BD PhaSeal™ Optima Protector (P13-O Multi)	IIa
515064	BD PhaSeal™ Optima Protector (P20-O)	IIa
515065	BD PhaSeal™ Optima Protector (P20-O Multi)	IIa
515067	BD PhaSeal™ Optima Protector (P32-O)	IIa
515070	BD PhaSeal™ Optima Connector (C35-O)	IIa
515078	BD PhaSeal™ Optima Infusion Adapter (C100-O)	IIa
515079	BD PhaSeal™ Optima Infusion Adapter (C100-O Multi)	IIa
515100	BD PhaSeal Protector (P14)	IIa
515102	BD PhaSeal Protector (P21)	IIa
515105	BD PhaSeal Protector (P50)	IIa
515107	BD PhaSeal Protector (P53)	IIa
515103	BD PhaSeal Protector (P21 Multi)	IIa
515104	BD PhaSeal Protector (P28)	IIa



515106	BD PhaSeal Protector (P50 Multi)	IIa
515117	BD PhaSeal Protector (P55)	IIa
515001	BD PhaSeal Injector Luer (N30C)	IIa
515003	BD PhaSeal Injector Luer Lock (N35)	IIa
515004	BD PhaSeal Injector Luer Lock (N35C)	IIa
515005	BD PhaSeal Injector Luer Lock (N35C Multi)	IIa
515200	BD PhaSeal Connector Luer Lock (C35)	IIa
515202	BD PhaSeal Connector Luer Lock (C45)	IIa
515303	BD PhaSeal Infusion Adapter (C70)	IIa
515306	BD PhaSeal Infusion Adapter (C100)	IIa
515307	BD PhaSeal Infusion Adapter (C100 Multi)	IIa
515300	BD PhaSeal Infusion Set (C50)	IIa
515302	BD PhaSeal Secondary Set (C61)	IIa
515304	BD PhaSeal Y-site Connector (C80)	IIa
515305	BD PhaSeal L Connector (C90)	IIa

Authorised Signatory:	
Name & Title:	Manoja Ranawake Vice President, Regulatory Affairs - EMEA, WWIPD & OUS Infection Prevention
On behalf of:	BD Switzerland Sàrl
Place of Issue:	Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
Date of Issue:	22-Jan-2024
Signature:	<div>DocuSigned by: <i>Manoja Ranawake</i></div> <div> Signer Name: Manoja Ranawake Signing Reason: I approve this document Signing Time: 22-Jan-2024 5:25:59 AM PST 2AD6595CC68E40A7BDC5BF23CE303120</div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
A	First release under the MDR (EU) 2017/745.
B	Full release of all PhaSeal and PhaSeal Optima devices under the MDR (EU) 2017/745.