DECLARATION OF CONFORMITY

Pottery Road,
Dun Laoghaire,
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bd.com

BD PhaSeal

Manufacturing Site:	**Manufactured on behalf of Becton, Dickinson and Company, Limited by:** **Becton Dickinson S.A.** Camino Valdeoliva s/n, 28750 San Agustín de Guadalix , Madrid, Spain. (All except: reference numbers listed immediately below) **Carefusion BH 335 d.o.o Cazin** Mihaljevac bb, 77220 Cazin, Bosnia and Herzegovina (515302) **Sendal S.L.** Crtra. Nacional Madrid-Caceres s/n 10350 Almaraz, Caceres, Spain (515300, 515303, 515312, 515313, 515314, 515315, 515316, 515320, 515321) **Medisize CZ** Tovární 560, 374 15 Trhové Sviny, Czech Republic (515301)
Products:	**BD PhaSeal (see attached list for the different types)**
Classification:	**Class IIa, Rule 2**
Conformity Assessment Route:	**Annex VII and Annex V**
GMDN:	**See attached products list**

We herewith declare that for the above mentioned products, their product design meets the provisions of the European Medical Device Directive 93/42/EEC of 14 June 1993 and Irish Regulation; S.I. No. 252 of 1994 (as amended by Regulation 5 of S.I. 110/2009) concerning medical devices. All supporting documentation is retained at the premises of the manufacturer or subcontractor.

Harmonized standards:	**EN 556-1:2001/AC:2006, ENISO 15223-1:2016, EN 1041:2008, EN 1707:1996, EN 20594-1:1993; EN IS0 10993-1:2009, EN IS010993-3:2014, EN IS0 10993-4:2009, EN IS0 10993-5:2009, EN IS010993-6:2009, EN IS0 10993-7:2008, , EN IS0 10993-11:2009, EN IS010993-12:2012, EN IS010993-15:2009, EN IS0 10993-17:2009, EN IS0 10993-18:2009; EN ISO11135-1:2014; EN ISO 11138-2:2009; EN ISO 11737-1:2006; EN ISO 11737-2:2009; EN ISO 11607-1:2009, EN ISO 11607-2:2006; EN ISO 13485:2016; EN ISO 14971:2012, EN 14155-1:2011**
Non -Harmonised Standards	**ISO 14644-1:1999; EN IS010993-2:2009; EN IS010993-10:2010, EN IS010993-10:2013; ISO 9626: 1995; ISO 2859-1:1999**
Notified Body:	**Intertek Semko AB,** Torshamnsgatan 43, Box 1103, 164 22 Kista, Sweden. **Number of Notified Body: 0413**
CE Certificate number:	**41319062-02**
Date of issue of original CE certificate:	**24 July 2012**

Date: **19 March 2021**

Name **Andrew Roche**
Function **QA/RA**

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CATALOG No.	PRODUCT	GMDN
515001	BD PhaSeal Injector Luer (N30C)	Code: **64467** **Term:** Luer /non-ISO 80369-standardized linear connector, single use Definition: A small, non-powered, non-invasive, tubular, two-way/linear connector with a Luer connection (either lock or slip) at one end and a connection which is not designed according to ISO 80369 (standard for small-bore connectors for liquids and gases) at the other end (typically barbed, bayonet, collet, conical, threaded or non-Luer-slip) intended to connect two luminal devices (e.g., catheter, tubing, container) with each other. It may have a straight or elbow shape; it does not incorporate a filter, valve, clamp, tubing nor puncturing component. This is a single-use device.
515003	BD PhaSeal Injector Luer Lock (N35)	
515004	BD PhaSeal Injector Luer Lock (N35C)	
515005	BD PhaSeal Injector Luer Lock (N35C Multi)	
515200	BD PhaSeal Connector Luer Lock (C35)	
515202	BD PhaSeal Connector Luer Lock (C45)	
515304	BD PhaSeal Y-Site Connector (C80)	
515052	BD PhaSeal Optima Injector (N35-O)	
515053	BD PhaSeal Optima Injector (N35-O Multi)	
515056	BD PhaSeal Optima Injector (N40-O)	
515057	BD PhaSeal Optima Injector (N40-O Multi)	
515070	BD PhaSeal Optima Connector (C35-O)	
515100	BD PhaSeal Protector (P14)	Code: **60537** Term: Vial/bottle adaptor, hermetic Definition: A device intended to be fitted to a vial or bottle to enable the airtight removal of its contents (e.g. medication) into a syringe, for subsequent administration to a patient. It is typically a housing that attaches to or replaces the
515102	BD PhaSeal Protector (P21)	
515103	BD PhaSeal Protector (P21Multi)	
515104	BD PhaSeal Protector (P28)	
515105	BD PhaSeal Protector (P50)	
515106	BD PhaSeal Protector (P50 Multi)	
515107	BD PhaSeal Protector (P53)	
515117	BD PhaSeal Protector (P55)	
515060	BD PhaSeal Optima Protector (P13-O)	

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515062	BD PhaSeal Optima Protector (P13-O Multi)	container lid, plus a Luer connection and sealed expansion chamber (e.g., balloon), allowing for pressure equalization intended to prevent the egress and ingress of materials (e.g., vapors, microbes). This is a single-use device.
515064	BD PhaSeal Optima Protector (P20-O)	
515065	BD PhaSeal Optima Protector (P20-O Multi)	
515300	BD PhaSeal Infusion Set (C50)	Code: 58977 Term: Intravenous administration set, Definition: A collection of noninvasive devices designed to conduct fluids from an intravenous (IV) administration bag/bottle to a peripheral venous cannula (not included) during gravitational or pump administration to a patient's venous system; some types may in addition be intended for enteral feeding applications. It typically includes tubing, connectors, chambers, clamps; the bag/bottle may be included. It does not include devices intended for invasive use nor a heat exchanger. This is a single-use device
515301	BD PhaSeal Secondary set with Drip Chamber (C60)	
515302	BD PhaSeal Secondary Set (C61)	
515312	BD PhaSeal Secondary Set (C62)	
515313	BD PhaSeal Secondary Set (C63 OP)	
515314	BD PhaSeal Secondary Set (C64)	
515315	BD PhaSeal Secondary Set (C65 OP)	
515316	BD PhaSeal Secondary Set w/0.2µm filter (C66)	
515320	BD PhaSeal Secondary Set (C81)	
515321	BD PhaSeal Secondary Set (C82 OP)	
515303	BD PhaSeal Infusion Adapter (C70)	
515305	BD PhaSeal L Connector (C90)	
515306	BD PhaSeal Infusion Adapter (C100)	Code: **64977** Term: Non-ISO 80369 formatted bag access spike Definition: A small, noninvasive, tubular connector with a small-bore connection/port, none of which is designed according to ISO 80369 (non-ISO80369 formatted), and a hollow bag-
515307	BD PhaSeal Infusion Adapter (C100 Multi)	
515078	BD PhaSeal Optima Infusion Adapter (C100-O)	

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515079	BD PhaSeal Optima Infusion Adapter (C100-O Multi)	access spike (either blunt or sharp) intended to connect an intravenous (IV) fluid or blood bag to a fluid line for administration to a patient. It may include a built-in air filter and drip chamber; it does not include tubing (i.e., not a tubing set) or any Luer formatted connections. This is a single-use device.