

Free Sales Certificate

FOR THE HEALTH AUTHORITIES OF CHILE

Certificate n° 00021028

Valid until 22.02.2027

The SWISS AGENCY FOR THERAPEUTIC PRODUCTS, SWISSMEDIC, authorizes and supervises therapeutic products (medicinal products and medical devices). In Switzerland medical devices are regulated under the Federal Act on Medicinal Products and Medical Devices (TPA; SR 812.21), the Medical Devices Ordinance (MedDO; SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219). On the basis of the documents submitted, Swissmedic certifies that the device(s) of the medical device category specified hereunder can be placed on the market in Switzerland without restrictions.

- see attached list of 2 page(s)

Companies involved in the manufacturing or the supplying of these medical devices:

- **Ordering company:** BD Switzerland Sàrl, 17 Route de Crassier Business Park Terre-Bonne, Bâtiment A4, 1262 Eysins, CH (Role: Legal manufacturer)

Bern, 22.02.2024

Swiss Agency for Therapeutic Products

Medical Devices Division


Jessica Wüthrich





APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. País: CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Jessica Wüthrich

3. actuando en calidad de funcionaria

4. se halla sellado/timbrado con Swissmedic

Instituto suizo de los productos terapéuticos

Certificado

5. en Berna

6. el 28. Feb. 2024

7. por Alessandra Manoiero
funcionaria de la Cancillería de la Confederación Suiza

8. con el número 004870

9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza

A. Manoiero

Tasa CHF 20.-





Legal Manufacturer for all product codes detailed in this list:

Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland.

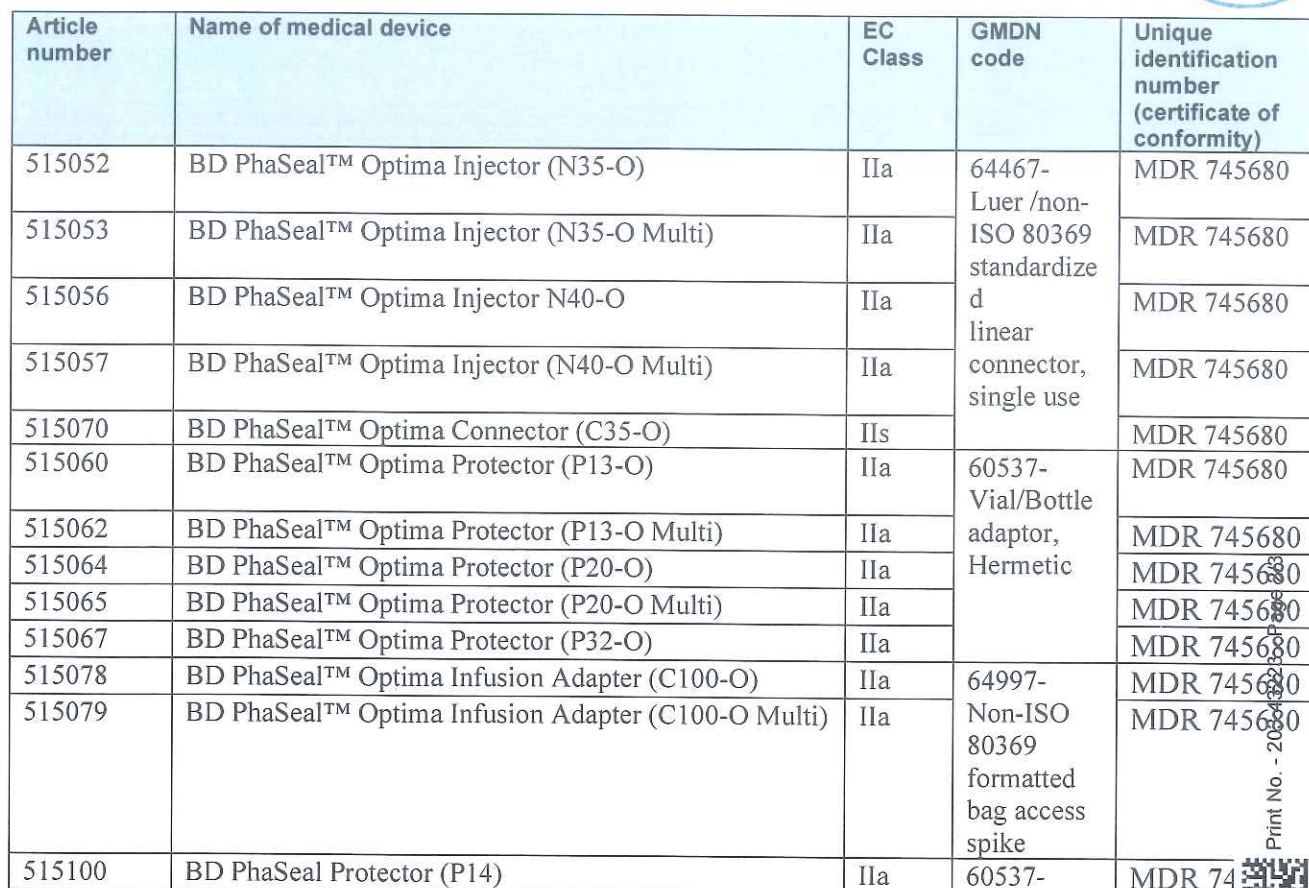
Becton Dickinson S.A.

Camino de Valdeoliva, s/n C.P. 28750, San Agustín de Guadalix, Spain

AB Nolatovagen, Torekov Skane Lan, Sweden 269 04

Nacional Madrid-Caceres s/n 10350 Almaraz, Caceres Spain

BH 335 d.o.o Cazin Mihaljevac, 77220 Cazin Bosnia & Herzegovina





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Terre Bonne Park – A4,
Route de Crassier 17,
1262 Eysins,
Switzerland.
+41 21 556 30 00 tel
+41 21 556 30 99 fax
www.bd.com

Article number	Name of medical device	EC Class	GMDN code	Unique identification number (certificate of conformity)
515102	BD PhaSeal Protector (P21)	IIa	Vial/Bottle adaptor, Hermetic	MDR 745680
515105	BD PhaSeal Protector (P50)	IIa		MDR 745680
515107	BD PhaSeal Protector (P53)	IIa		MDR 745680
515103	BD PhaSeal Protector (P21 Multi)	IIa		MDR 745680
515104	BD PhaSeal Protector (P28)	IIa		MDR 745680
515106	BD PhaSeal Protector (P50 Multi)	IIa		MDR 745680
515117	BD PhaSeal Protector (P55)	IIa		MDR 745680
515001	BD PhaSeal Injector Luer (N30C)	IIa	64467- Luer /non-ISO 80369 standardized linear connector, single use	MDR 745680
515003	BD PhaSeal Injector Luer Lock (N35)	IIa		MDR 745680
515004	BD PhaSeal Injector Luer Lock (N35C)	IIa		MDR 745680
515005	BD PhaSeal Injector Luer Lock (N35C Multi)	IIa		MDR 745680
515200	BD PhaSeal Connector Luer Lock (C35)	IIa		MDR 745680
515202	BD PhaSeal Connector Luer Lock (C45)	IIa		MDR 745680
515303	BD PhaSeal Infusion Adapter (C70)	IIa	58977 - Intravenous administration Sets	MDR 745680
515306	BD PhaSeal Infusion Adapter (C100)	IIa	64997- Non-ISO 80369 formatted bag access spike	MDR 745680
515307	BD PhaSeal Infusion Adapter (C100 Multi)	IIa		MDR 745680
515300	BD PhaSeal Infusion Set (C50)	IIa	58977 - Intravenous administration Sets	MDR 745680
515302	BD PhaSeal Secondary Set (C61)	IIa		MDR 745680
515304	BD PhaSeal Y-site Connector (C80)	IIa		MDR 745680
515305	BD PhaSeal L Connector (C90)	IIa		MDR 745680
515404	Cap for Injector (M50)	Is	65151 - Non-ISO 80369 - Standardized fluid path protective cover	MDR 745680
515406	Connector Cap (M70)	Is		MDR 745680
515085	BD PhaSeal Optima Infusion Clamp (M25-O)	I	63390- Intravenous line closed infusion system clamp	MDR 745680

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