

Dispointro-x-safe: with small wings and without injection port with safety feature

1. PRODUCT DESCRIPTION

Safety I.V. Cannula/Catheter is a device for access to the human circulatory system for introduction of fluids or medicament and/or withdrawal of blood samples. It comprises of a short flexible plastic FEP/PUR/PTFE tube (the Catheter) etc., which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded. Duration of Use: Short Term.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device (classification as per ANNEX–VIII of EU MDR 2017/745).

3. INTENDED USE

Safety I.V. Cannula is a device used for introduction of fluids or medicament and/or withdrawal of blood samples through peripheral vein. It is inserted into a vein over a hollow introducer needle after which the needle is withdrawn and discarded. Safety I.V. Cannula eliminates the chances of needle stick injuries and blood borne infections to the healthcare providers during needle withdrawal and disposal. It is used by following aseptic technique. The use of the product is restricted to a qualified doctor or a paramedic.

4. MATERIAL OF CONSTRUCTION

S. No.	Component	Material Used
1.	Needle	Stainless Steel
2.	Teflon Holder	POM
3.	X Type Clip	Stainless Steel
4.	Needle Hub	PP
5.	Needle Cover	PP
6.	Catheter	FEP/PUR/PTFE
7.	Flow Control	PP

5. PRODUCT SPECIFICATION

S. No.	Product	Gauge/Size	GMDN Code	Classification
1.	**Dispointro-X-Safe**	18G, 20G, 22G ,24G & 26G	64574	Rule-7, IIa

6. REFERENCE COMPLIANCE STANDARD

S.No.	Name Of Standard	Standards
1.	Intravascular Catheters- Sterile and single use catheters-Part 1- General requirements	EN ISO 10555-1:2023
2.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	EN ISO 15223-1:2021
3.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of sterilization process for medical devices.	EN ISO 11135:2014, EN ISO 11135:2014/A1:2019
4.	Sterilization of health care products - Biological indicators - Part 1: General requirements.	EN ISO 11138-1:2017
5.	Sterilization of health care products-Microbiological methods - Part 1: Determination of a population of microorganism on products.	EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021
6.	Biological evaluation of medical devices - part 1, Evaluation and testing within a risk management process.	EN ISO 10993-1: 2020
7.	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	EN ISO 10993-3:2014
8.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	EN ISO 10993-4:2017
9.	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	EN ISO 10993-5:2009
10.	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation.	ISO 10993-6:2016
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7:2008
12.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	EN ISO 10993-11:2018
13.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	EN ISO 10993-12:2021
14.	Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances.	EN ISO 10993-17:2023
15.	Medical devices-Quality management systems-Requirements for regulatory purposes.	EN ISO 13485:2016

		EN ISO 13485:2016/A11:2021, EN ISO 13485:2016/AC:2018
16.	Medical devices-application of risk management to medical devices.	EN ISO 14971:2019, EN ISO 14971:2019/A11:2021
17.	European council directive concerning medical devices.	MDD 93/42/EEC , 2007/47/EC
18.	Intravascular Catheters- Sterile and single use catheters-Part 2-Over -needle peripheral catheters.	EN ISO 10555-5:2013
19.	6% Luer- Small-bore connectors for liquids and gases in health care application.	EN ISO 80369-7:2021

7. PACKAGING DETAILS:

S. NO.	Type of Packaging	No. of Pieces
1.	Blister Pack (Tyvek / PVC film) Blister Pack (MG paper / PVC film)	01
2.	Inner (Duplex) Box	100
3.	Outer/Master Carton (Corrugated box)	1000

8. OTHER DETAILS;

Intended Use: Refer the instruction for use before the application.

Storage: Store in a cool and dry place and keep away from direct sunlight and extreme heat.

Method of Sterilization: Sterilized using ethylene oxide.

Shelf life: 05 years from the month / date of sterilization.

Testing and Analysis: Testing for sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, penetration force, packaging integrity, etc.) is performed on each batch before release.

Biocompatibility: The product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

Disposal: Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

7. COMPLIANCE INFORMATION

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Sec-59, Phase-II, Ballabgarh,Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106

QMS Certification: EN ISO 13485:2016**,** TUV SUD Product Service GmbH

CE Marking: TUV SUD Product Service GmbH, EC Notified body No. 0123

GMDN:64574

8. ABBREVIATIONS

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature
I.V. Cannula – Intravenous Cannula
MKP – Medical Kraft Paper