



1. PRODUCT DESCRIPTION

Injection Stopper is made of plastic with a stopper on one end and 6% male connection at other end. It is used as an accessory with I.V. Cannula and extension tubes. Material of Composition: Isoprene, ABS.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class Is / Rule 2, medical device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

Injection Stopper is used as a protective cap and also as intermittent intravenous device for administration of medicaments.

4. PRODUCT FEATURES

- Universal 6% Taper as per ISO 80369-7, compatible with any standard product.
- Latex/Isoprene plug leakage fitting for drawing of blood samples or injection intermittent medicine.
- Minimal Dead Space.
- Individually packed in right blister.
- 6% Taper Face.
- Sterile/Non-Pyrogenic/Single use.
  Option Available: Transparent Body, Latex/Isoprene

5. PRODUCT VARIANTS

Following options are available with the product Injection Stopper:

- Injection Stopper-Yellow Isoprene.
- Injection Stopper-Yellow Latex.
- Injection Stopper-Transparent Isoprene.
- Injection Stopper-Transparent Latex.

6. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	Heparin Cap	ABS
2.	Site	Poly Isoprene /Latex rubber

7. PRODUCT SPECIFICATION

S.N	Product	Colour	GMDN Code	Classification	Rule
1	Injection Stopper/ Heparin Cap	Transparent and Yellow	16858	Class-Is	Rule 2

8. PACKAGING DETAILS:

ITEM	MATERIAL	QUANTITY
Primary Packing	Blister Pack	250 pcs
Inner Carton	Kraft Pulp Paper	2500 pcs
Master Carton	Kraft Pulp Paper	10000 pcs

9. REFERENCE COMPLIANCE STANDARD

S. NO.	Title	Standard Ref. No.
1.	Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment	EN ISO 8536-10:2015
2.	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	EN ISO 80369-7:2021
3.	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999 IS 2500-1:2000
4.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
5.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014
6.	Sterilization of health care products - Biological indicators -Part 1: General requirements	EN ISO 11138-1:2017
7.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms onproducts	EN ISO 11737-1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
10.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2020
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008/And 1:2019(en)
12.	Medical devices – application of risk management to medicaldevices	EN ISO 14971:2019
13.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
14.	Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016

15.	Medical devices - Information to be supplied by themanufacturer	ISO 20417:2021
16.	European council directive concerning medical devices	MDD 93/42/EEC , 2007/47/EC
17.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
18.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
19.	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood	ISO 10993-4:2017
20.	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
21.	Biological evaluation of medical devices Part 10: Tests for skin sensitization	ISO 10993-10:2021
22.	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	ISO 10993-11:2017
23.	Biological evaluation of medical devices Part 12: Sample preparation and reference materials	ISO 10993-12:2021
24.	Medical devices Part 1: Application of usability engineering to medical devices	IEC 62366-1:2015

10. 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 (Visual Checking, Moulding defect, Packaging Condition, Fitment test, 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.

11.COMPLIANCE INFORMATION

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016**,** TUV SUD Product Service GmbH
CEMarking: TUV SUD Product Service GmbH, EC Notified body

No. 0123
GMDN CODE: 16858

12. ABBREVIATIONS

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature

Prepared by:	Reviewed by:	Approved by:	Issued by:	
Name: Harpreet Kaur Desig.: Executive, QA	Name: Hardik Bhan Desig.: Sr. Executive, QA	Name: Krishanu Bose Desig.: General Manager	Name: Hardik Bhan Desig.: MR	DISPOSAFE HEALTH AND LIFE CARE LTD.