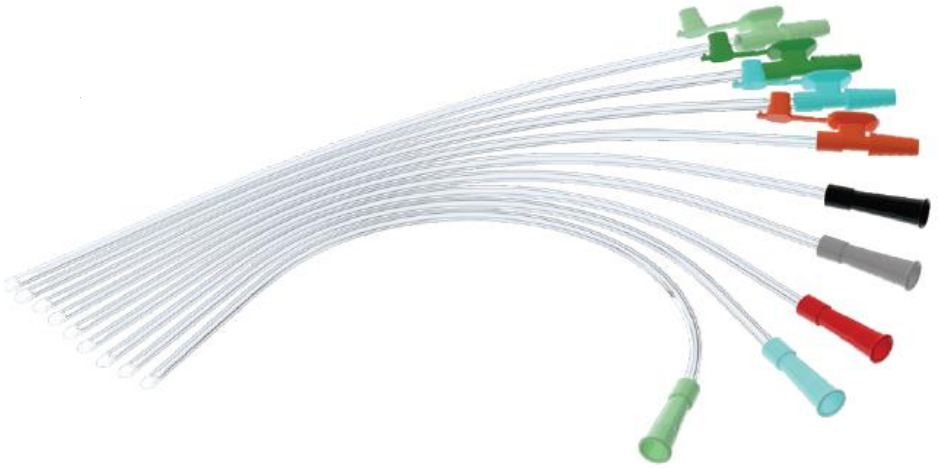
	DISPOSAFE HEALTH AND LIFE CARE LTD	REF.: DS-TDS-014
Disposafe We Touch.... Lives!	TECHNICAL DATA SHEET SUCTION CATHETER	REVISION NO.: 00 DATE: 10.01.2024



1. PRODUCT DESCRIPTION

A suction catheter connects to a suction machine or collection canister. The major components are PVC tube, colour coded connector.

This is a single use device. **Duration of Use:** Short term.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 5, medical device(classification as per ANNEX – VIII of MDD/93/47/EEC amended as 2007/47/EEC)

3. INTENDED USE

Intended use for removal of secretion from mouth, trachea and bronchial tube uses in respiratory tract. It is provided with universal funnel shape connection for safe connection to standard suction equipment.

4. PRODUCT FEATURES

- Suction catheter is a long flexible tube which is used in invasive case to remove secretion from the mouth and airway of critical patients. This catheter is attached to a collection container and device that generate suction.
- Manufactured from Non-toxic, DEHP Free P.V.C Tube.
- Universal colour connector for size identification and secure connection with suction connector.
- Distal end open with lateral eye to avoid trauma during suction of oral-bronchial secretion.
- Frost finished or clear tube along with atraumatic eyes for smooth intubation.
- Graduated marked for correct position of catheter.
- Length 50 cm
- Sterile, Non-Pyrogenic
- Available sizes: 8FG to 20FG.
- Straight peel open pack & individually wrapped in a peel away pack.

Prepared by:	Reviewed by:	Approved By:	Issued By:	
				DISPOSAFE HEALTH AND LIFE CARE LTD.

5. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1	PVC tube	Poly vinyl Chloride (PVC)
2	Thumb Control Connector	Poly vinyl Chloride (PVC)

6. PRODUCT SPECIFICATION

Gauge	Colour of Connector	Packing Inner/ Outer Unit
8FG	Blue	100/600
10G	Black	100/600
12FG	White	100/600
14FG	Green	100/600
16FG	Orange	100/600
18FG	Red	100/600
20FG	Yellow	100/600

S.No	Characteristics	Specified	Tolerance
1.	Effective length of tube	500 mm (50cm)	± 10% (± 5cm)
2.	OD of Tube	As per control drawing	± 0.05 mm
3.	ID of tube	As per control drawing	± 0.05 mm
4.	Colour code	As per standard	----
5.	Connecting ports	6% Male Taper on one end & 6%Female taper on other end with Luer lock facility	
6.	Eye distance	15mm	
7.	Funnel length	37mm ± 1mm	
8.	Printed/Non printed	Printed/Non printed	

7. REFERENCE COMPLIANCE STANDARD

8.

S No.	Name of Standard	Standard Number
Harmonized standards		
1.	Suction Catheters for use in the Respiratory Tract	ISO 8836 : 2019
2.	Sampling Procedure For Inspection By attributes	ISO 2859-1:1999
3.	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	EN ISO 15223-1:2021
4.	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
5.	Sterilization of health care products - Biological indicators - Part 1: General requirements.	EN ISO 11138-1:2017
6.	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
7.	Biological evaluation of medical devices - part 1, Evaluation and testing within a risk management process.	EN ISO 10993-1: 2018
8.	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	EN ISO 10993-3:2014
9.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood.	EN ISO 10993-4:2017
10.	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.	EN ISO 10993-5:2009
11.	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation.	EN ISO 10993-6:2009
12.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7:2008 And 1:2019
13.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	EN ISO 10993-11:2017
14.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	EN ISO 10993-12:2021

15.	Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances.	EN ISO 10993-17:2009
16.	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
17.	Medical devices-application of risk management to medical devices.	EN ISO 14971:2019, EN ISO 14971:2019/A11:2021
18.	European council directive concerning medical devices.	MDD 93/42/EEC , 2007/47/EC

9. OTHER DETAILS

Intended Use: Intended use for removal of secretion from mouth, trachea and bronchial tube uses in respiratory tract. It is provided with universal funnel shape connection for safe connection to standard suction equipment.

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.

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.

10. PACKAGING INFORMATION

Primary Unit Packaging: Soft blister

Secondary Packaging: Duplex.

Tertiary Packaging: Corrugation Box

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

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

GMDN: 34923