TECHNICAL DATA SHEET

TRACHEOSTOMY TUBE

DOCUMENT REF.	REVISION NO.	REVISION DATE	CLASSIFICATION
DS-TDS-069	00	02-06-2026	Class IIa · Rule-5

01 INTENDED USE

The intended use of Tracheostomy tube is for intubation in Trachea. It helps patient breathe following a tracheostomy (a surgical procedure that creates a small opening in the neck directly into the windpipe, or trachea). A tracheostomy tube is placed through the neck opening to allow a patient to breathe through the tube instead of through their mouth or nose. It can be attached with an active medical device.

02 DEVICE DESCRIPTION

Standard components of the tracheostomy tube include the hub, flange, outer cannula, inner cannula, cuff, pilot balloon and inflation line. A tracheostomy tube is made of PVC. It is a single use device.

Duration of Use: The device is intended for short-term or long-term use, depending on the patient's clinical condition and the physician's judgment. The tracheostomy tube may remain in place for days, weeks, months, or longer as required to maintain a patent airway and facilitate respiratory support. The device should be monitored regularly and replaced or removed when clinically indicated, in accordance with established medical protocols and patient needs.

#	Product	Type	Classification
01	Tracheostomy Tube	Standard	IIa / Rule-5 (as per EU MDR 2017/745) Class B (as per IMDR)

03 HARMONIZED STANDARDS

No.	Standard Description	Reference Number
01	Sterile drainage catheters and accessory devices for single use	EN ISO 20697:2018
02	Sampling Procedure For Inspection By Attributes	ISO 2859-1:1999/Amd 1:2011
03	Clean Rooms and Associated Controlled Environments — Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
04	Clean Rooms and Associated Controlled Environments — Monitoring evidence of cleanroom performance related to air cleanliness	EN ISO 14644-2:2015
05	Medical devices — Symbols for labels, labeling and information to be supplied — Part 1: General requirements	EN ISO 15223-1:2021

No.	Standard Description	Reference Number
06	Sterilization of health-care products — Ethylene oxide — Development, validation and routine control of sterilization process	EN ISO 11135:2014/Amd 1:2018
07	Sterilization of health care products — Biological indicators — Part 1: General requirements	EN ISO 11138-1:2017
08	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
09	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
10	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
11	Sterilization of health care products — Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
12	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2018
13	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
14	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
15	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
16	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
17	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
18	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2010
19	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	EN ISO 10993-11:2017
20	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021

No.	Standard Description	Reference Number
21	Medical devices — Quality management systems — Requirements for regulatory purposes	EN ISO 13485:2016
22	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019
23	Clean rooms and associated controlled environments — Biocontamination control — General principles and methods	EN ISO 14698-1:2003

04 CONSTRUCTION OF MATERIAL

Tracheostomy Tube

No.	Component Description	Material
01	Tracheostomy Tube	PVC- Poly Vinyl Chloride

05 PRODUCT FEATURES

- Tracheostomy tubes uncuffed plain with reusable inner cannula manufactured of high quality, compliant material
- Plain inner cannula with integral 15mm twist-lock connector to allow connection of ancillary equipment and can be cleaned to maintain airway patency
- Smooth, rounded-tip obturator facilitates insertion
- Latex-free
- Sterile
- Supplied individually wrapped in a peel away pack
- Size: ID 7.5mm, OD 12.2mm, Length 79mm

06 COMPLIANCE INFORMATION

MANUFACTURER

Disposafe Health and Life Care Ltd.
Plot No. 1 & 2, Sec-59, Phase-II, Ballabhgarh, Faridabad – 121004, Haryana, India

REGULATORY DETAILS

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

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

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

GMDN Code: 38566

07 ABBREVIATIONS

QMS — Quality Management System
GMDN — Global Medical Device Nomenclature
IVC — Intravenous Cannula / Catheter
MKP — Medical Kraft Paper
UMDNS — Universal Medical Device Nomenclature System
EO — Ethylene Oxide
PC — Polycarbonate
HDPE — High-Density Polyethylene
LDPE — Low-Density Polyethylene
PVC — Polyvinyl Chloride

08 AUTHORIZATION

PREPARED BY — QA/RA	REVIEWED BY — MANAGER, QA/RA	APPROVED BY — GENERAL MANAGER	ISSUED BY — MR
			
Date: 02-06-2026	*Date: 02-06-2026*	*Date: 02-06-2026*	*Date: 02-06-2026*