



1. PRODUCT DESCRIPTION

The Endotracheal Tube is a tube constructed of polyvinyl chloride that is placed between the vocal cords through the trachea. The major components are graduated PVC tubing with eye cuts, connector, (ET tube with cuff) a balloon is attached at the proximal end and a non-return valve is attached at distal end to inflate and deflate the balloon. It is a single use device. Duration of Use: Short term. Material of Composition: PVC, SS, Silicon, PP.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 5, device as per EU MDR 2017/745 Annexure VIII.

3. INTENDED USE

An endotracheal tube is used in general Anesthesia. The E.T. Tube is placed between the vocal cords and through the trachea. The E.T Tube can be used to assist with breathing during following conditions: - Lungs disease, chest trauma, airway obstruction, during surgery under general anesthesia, severe pneumonia, collapsed lung, removal of foreign object lodges in the airway. It also prevents the contents of the stomach for getting into the lungs during massive gastrointestinal bleed.

4. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product	GMDN Code	Classification
1.	Endotracheal tube (Plain, Cuffed & Reinforced)	14085	Rule-5, Class-IIa

5. MATERIAL OF CONSTRUCTION

S. No.	Component/Parts	Material used
1.	Main Tube (Cuffed)	Polyvinyl chloride Soft
2.	Connector	Polypropylene
3.	Cuff	Polyvinyl chloride Soft

4.	NRV	a. Body – R. PVC b. Plunger Cap – POM c. Body Cap – R. PVC d. Plunger – POM e. Spring – SS 304 f. Washer – Silicon
5.	Pilot balloon	Polyvinyl chloride Soft
6.	Pilot Tube	Polyvinyl chloride Soft

6. PRODUCT SPECIFICATION

TYPE					Packing (Inner / Outer)
S.No.	**Plain Cuffed SIZE (mm)**	**Plain Without Cuff SIZE (mm)**	**Cuffed, Reinforced SIZE (mm)**	**Without Cuff, Reinforced SIZE (mm)**	
1)	2.0	2.0	2.0	2.0	25/300
2)	2.5	2.5	2.5	2.5	25/300
3)	3.0	3.0	3.0	3.0	25/300
4)	3.5	3.5	3.5	3.5	25/300
5)	4.0	4.0	4.0	4.0	25/300
6)	4.5	4.5	4.5	4.5	25/300
7)	5.0	5.0	5.0	5.0	25/300
8)	5.5	5.5	5.5	5.5	25/300
9)	6.0	6.0	6.0	6.0	25/300
10)	6.5	6.5	6.5	6.5	25/300
11)	7.0	7.0	7.0	7.0	25/300
12)	7.5	7.5	7.5	7.5	25/300
13)	8.0	8.0	8.0	8.0	25/300
14)	8.5	8.5	8.5	8.5	25/300
15)	9.0	9.0	9.0	9.0	25/300
16)	9.5	9.5	9.5	9.5	25/300
17)	10.0	10.0	10.0	10.0	25/300

- Endotracheal tube with inflatable cuff.
- Open distal end with left-facing bevel (approx. 38° ±10°) and atraumatic tip.
- Murphy's eye provided.
- High-volume, low-pressure (HVLP) cuff near distal end.
- Cuff inflates symmetrically and does not extend beyond distal tip or block Murphy's eye.
- Integrated inflation line with non-return valve, Luer connector, and pilot balloon.
- Magill-type anatomical curvature.
- Clear centimetre graduations.
- Continuous radio-opaque line for X-ray visibility.
- Standard 15 mm OD connector at proximal end.
- Made of transparent, medical-grade PVC.
- Individually packed.
- Sterile, single-use product.

- Sterilized by Ethylene Oxide (EO) or Gamma Radiation (specify method).
- Latex-free.

7. REFERENCE COMPLIANCE STANDARD

S.No.	Name of Standard	ISO Std. No.
Standard for Endotracheal Tube		
1.	Anaesthetic and respiratory equipment -- Tracheal tubes and connectors	EN ISO 5361:2023
2.	Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2021
3.	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1:1999/Amd 1:2011
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	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
6.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization	ISO 11135:2014/Amd 1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2019/Amd 1:2023
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2019/Amd 1:2023
10.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2018
11.	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
12.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
13.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
14.	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
15.	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	ISO 10993-7:2008/Amd 1:2019
16.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
17.	Biological evaluation of medical devices - Part 11 : Tests for systemic	EN ISO 10993-

	toxicity	11:2017
18.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	ISO 10993-12:2021
19.	Biological evaluation of medical devices- Part 17 : Establishment of allowable limits for leachable substances	EN ISO 10993-17 :2023
20.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016
21.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
22.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
23.	Clean rooms and associated controlled environments- bio- contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
24.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366: 2015
25.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
26.	Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	EN ISO 11737-2:2020

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing (Blister)	Soft Blister/Paper Pouch
Inner Carton	3 Ply corrugation
Master Carton	5 Ply corrugation

9. OTHER DETAILS

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. 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 Code: 14085

ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature