

DISPOSAFE PRODUCT NAME	BRAND NAME
RYLES TUBE	Ryles-care

1. PRODUCT DESCRIPTION

The major components are PVC tube with closed end and graduation mark. It also has a Funnel at the distal end. 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 – IX of MDD/93/47/EEC amended as 2007/47/EEC)

3. PRODUCT CHARACTERISTICS & INTENDED USE

A nasogastric tube is a tube for short term nutritional support and also for aspiration of stomach contents. It is used to drain gastric contents, decompress the stomach, obtain a specimen of the gastric contents and administer medicine, liquid feeding.

- Soft tapered Luer connector at the proximal-end to fit easily with standard accessories.
- Color coded connector for easy identification of size.
- Manufactured from Non-toxic, Non-irritant medical grade PVC.
- Soft, frosted and kink resistance PVC tube with radio-opaque line marked at 50, 60 & 70cm for accurate placement.
- DEHP free tube
- Smooth, low friction surface facilitates easy introduction.
- Siliconized and smooth outer surface to reduce chances of tissue irritation.
- Sterile, individually packed

4. PRODUCT VARIANTS

Following variants are available for the products

S. No.	Product	Size	GMDN Code	Classification / Rule

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1.	Ryles Tube	6FG,8FG,10FG,12FG, 14FG, 16FG, 18FG, 20FG, 22FG	14199	Class-IIa, Rule-5

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5. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	PVC Tube	PVC
2.	Connector	PVC

6. PRODUCT SPECIFICATION

Size	Color	Packing Inner/ Outer Unit
4 FG	Red	50/500
5 FG	Grey	50/500
6 FG	Light Green	50/500
8 FG	Light Blue	50/500
10 FG	Black	50/500

7. REFERENCE COMPLIANCE STANDARD

S. No.	Title	Standard Ref. No.
1.	Enteral feeding system- Design and Testing.	ISO 20695:2020
2.	Small-bore connectors for liquids and gases in healthcare applications	ISO 80369 - 7 : 2016
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
4.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part1: 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

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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 on products.	EN ISO 11737-1:2018
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systemsand packaging systems.	EN ISO 11607-1:2019
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing andassembly 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: 2018
11.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7:2008
12.	Medical devices – application of risk management to medical devices.	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.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration.	EN ISO 14644-1:2015
16.	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

8. PACKAGING DETAILS and SPECIFICATIONS

ITEM	MATERIAL
Primary Packing	Pouch Packaging
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

Note: Labels conform to requirements of EC Medical Device Directive (MDD) 2007/47/EC and international labeling standards.

9. OTHER DETAILS

Intended Use: A nasogastric tube is a tube for short term nutritional support and also for aspiration of stomach contents. It is used to drain gastric contents, decompress the stomach, obtain a specimen of the gastric contents and administer medicine, liquid feeding.

- **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 (Particulate contamination, leakage, dimensions, Joint strength between tube and connector & sealing peel open force) 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.

10. COMPLIANCE INFORMATION

Manufacturing Site 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

CE Marking: TUV-SUD Product Services GmbH

GMDN: 14199

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