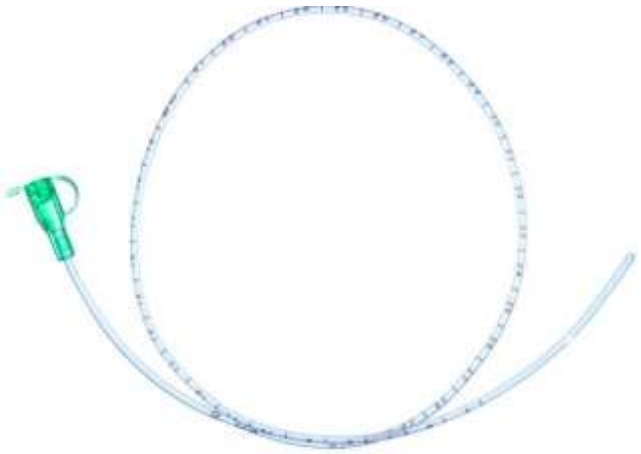


| DISPOSAFE PRODUCT NAME | BRAND NAME |
|---|---|
| **Infant Feeding Tube** | Dispofeedy |

## 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 – VIII of EU MDR 2017/745

## 3. PRODUCT CHARACTERISTICS & INTENDED USE

Infant Feeding Tube is a tube for short term nutritional support to administer medicine, liquid feeding to new-born babies.

- Graduation marking after every cm
- Closed distal end with two lateral eyes
- Soft, frosted & kink resistant PVC tubing with radio-opaque line
- Length : 40, 50 & 100 cm
- Sizes : 4 FG to 10 FG
- DEHP Free

### 4. PRODUCT VARIANTS

Following variants are available for the products

| S. No. | Product | Size | GMDN Code | Classification / Rule |
|---|---|---|---|---|

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

## 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 - Part 1: General requirements | EN ISO 15223-1:2021 |

| PREPARED | APPROVED |
|---|---|
| (QUALITY ASSURANCE) | (GENERAL MANAGER) |

| | | |
|---|---|---|
| 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<br>- Part 1: Determination of a population of microorganisms on products | EN ISO 11737-1:2018 |
| 8. | Packaging for terminally sterilized medical devices - Part 1:<br>Requirements for materials, sterile barrier systems and packaging systems | EN ISO 11607-1:2019 |
| 9. | Packaging for terminally sterilized medical devices - Part 2:<br>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: 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<br>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 | 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 |

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

## 9. OTHER DETAILS

- **Intended Use:** Infant Feeding Tube is a tube for short term nutritional support to administer medicine, liquid feeding to new-born babies.
- **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

DISPOSAFE HEALTH AND LIFECARE LIMITED FARIDABAD INDIA

| PREPARED | APPROVED |
|---|---|
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