

1. PRODUCT DESCRIPTION

Nelaton catheter are made from Non-toxic, non-irritant, Medical grade PVC Compound. Radio opaque line provided throughout the catheter for X-ray visualization. Distal end is coned with two lateral eyes for maximum drainage. Duration of Use: Short term.

2. DEVICE CLASSIFICATION AND RULE

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

3. PRODUCT CHARACTERISTICS

Primarily used for urinary drainage in patients with temporary urinary retention or those requiring catheterization for medical reasons. Healthcare providers utilize this type of catheter to access the bladder and facilitate the removal of urine effectively.

- Catheter is provided with atraumatic rounded catheter holes without risk of tissue damage when inserting, emptying and discontinuing the catheter.
- Siliconised smooth surface for non-traumatic intubation.
- Silicone coating ensures atraumatic introduction and protects against urethral irritation.
- Color coded Valve sleeve for easy identification of size.
- Large elliptical lateral eye.
- Plastic valve for effective inflation and deflation of balloon.
- Symmetrical large capacity balloon ensuring a straight tip for proper flow and good sphincter action thus preventing bladder leakage.
- Soft funnel for flexible and effective connection, avoiding urinary spills.
- Sterile/ Non-Pyrogenic /Single use.
- DEHP free P.V.C. tube is used.
- Nelaton Catheter surface is clear/frosted smooth.
- The distal end is conned for atraumatic cathterization.
- Two lateral eyes allow for efficient drainage.
- Universal, Gauge colour coded funnel shaped connector provide for easy connection to urine bag.

- Kink resistant tubing.

The product does not compromise with the clinical condition or the safety of patients. This device to be used in ambient conditions and use of the device is restricted to a qualified doctor or paramedic.

4. INTENDED USE

Nelaton catheter is used to clean intermittent Catheterization (CIC) treatment. It is intended for use by male, female and pediatric patient for draining urine from the bladder.

5. PRODUCT VARIANTS

Following variants are available for the products

S. No.	Product	GMDN Code	Classification/Rule
1.	**Nelaton catheter**	45603	Class-IIa/Rule-5

6. MATERIAL OF CONSTRUCTION

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

7. PRODUCT SPECIFICATION

S. No.	Size	Colour	Length
1.	6 FG	Light Green	38 cm
2.	8 FG	Light Blue	38 cm
2.	10 FG	Black	38 cm
3.	12 FG	White	38 cm
4.	14 FG	Green	38 cm
5.	16 FG	Orange	38 cm
6.	18 FG	Red	38 cm

8. REFERENCE COMPLIANCE STANDARD

S.No.	Name Of Standard	Standards
1)	Sterile urethral catheters for single use	EN ISO 20696:2018
2)	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
3)	Medical Devices - Application for Risk Management to Medical Devices	EN ISO 14971:2019
4)	Biological evaluation of medical devices. Part 1: Evaluation and testing as part of the risk management process	EN ISO 10993-1:2020
5)	Biological evaluation of medical devices. Part 3: Genotoxicity, carcinogenicity and reproductive toxicity tests	EN ISO 10993-3:2014
6)	Biological Evaluation of Medical Devices - Part 4: Selection of Tests Relevant to Blood Interactions	EN ISO 10993-4:2017
7)	Evaluation of the biological effects of medical devices - Part 5: In vitro cytotoxicity tests.	EN ISO 10993-5:2009
8)	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues.	EN ISO 10993-7:2008/ A1:2022
9)	Evaluation of the biological effects of medical devices - Part 11: Systemic toxicity tests	EN ISO 10993-11:2018
10)	Biological evaluation of medical devices - Part 12: Sample preparation and control samples	EN ISO 10993-12:2021
11)	Symbols used on medical device labels in labeling and information provided.	EN ISO 15223-1:2021
12)	Sterilization of medical devices - Microbiological methods - Part 1: Determination of the microbial population on products	EN ISO 11737-1:2018/ A1:2021
13)	European Union Medical Devices Regulation	MDR 2017/745
14)	Medical devices - Part - 1: Application of usability engineering to medical products.	IEC 62366-1:2015/Amd 1:2020
15)	Clinical Investigations of Medical Devices in Humans - Good Clinical Practice	EN ISO 14155:2020
16)	Sterilization of medical devices - Chemical indicator - Part 1 General requirements	EN ISO 11140-1:2015
17)	Medical devices-Post market Surveillance for manufacturer	ISO/TR 20416:2020

18)	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
19)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	ASTM-F1980

9. PACKAGING DETAILS and SPECIFICATIONS

ITEM	MATERIAL	Quantity
Primary Packing	Soft Blister	01
Inner Carton	400 GSM Khanna Make	100
Master Carton	3 Ply Corrugated Box	600

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)

QMS Certification: EN ISO 13485:2016

CE Marking: TUV-SUD Product Services GmbH

GMDN: 45603