

Nulife

Nulife is a global medical disposable solutions company with its footprint in 80+ countries and its headquarters in Mumbai, India.

With a workforce of over 2000 people worldwide, Nulife annually sells more than 300 million medical devices.

Triple Safety

Nulife Triple Safety is a brand that is committed to offering affordable healthcare solutions.

Powered by cutting-edge innovation, Nulife Triple Safety has disrupted the status quo in its sector through cost-effective healthcare products over the years.



Nulife Triple Safety Sterile Foley Balloon Catheter (Three-way)

Product Information

Nulife Foley Balloon Catheters are meticulously crafted to optimise their performance through careful design of balloon materials, tips and fluid channels.



Stringent measures are implemented to prevent balloon blockage, ensuring a smooth and trauma-free de-catheterisation process.

This commitment to quality allows us to deliver utmost comfort to patients during use.

Special Features

- Blockage-free balloon
- Trauma-free de-catheterisation
- Maximum fluid flow



TECHNICAL SPECIFICATION SHEET

Product Information

Product Name	Sterile Foley Balloon Catheter
Material	Natural Rubber Latex
Colour	Yellow
Design	Designed to ensure that the balloon material, tips and fluid channel provide the best possible performance and the highest degree of comfort to patients while in use
Sterilisation	Ethylene Oxide
Labelling	Shall comply with the corresponding labelling specification and customer requirement and ENISO 15223-1: 2021
Shelf Life	5 years from the date of manufacture
Storage Condition	Shall be stored in a cool, dry place and away from direct light at temperature 5°C to 40°C
Certifications	CE under EU MDR 2017/745, ISO 13485: 2016
Quality Standard	ISO 20696

Packaging Details

Packing	Three-way
Pouch	1 piece
Inner Box	10/20 pieces for three-way
Master Carton	200/400 pieces (10/20 inner boxes)

Variants

Variants	Sizes
Sterile Foley Balloon Catheter Three-way	16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr

Device Name	Sterile Foley Balloon Catheter
Catalogue No.	FBC3LE
Device Sizes	16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr
Device Variants placed in the Market	Three-way
Manufacturer(s) name and Address:	MRK Healthcare Pvt. Ltd. S. No. 153/P& 310, Panch Pippal, Hansapur Runi, Unjha-Patan Road, Patan 384 265 Gujarat, India.

Foley Balloon Catheter Specification (Three-way)									Standards
Surface Test	Should meet the requirements of ISO 20696								ISO 20696: 2018 (5.4)
Designated Size FG/Ch/Fr	16	18	20	22	24	26	28	30	ISO 20696: 2018 (5.5.2)
Outside Diameter ±0.33 (mm)	5.3	6.0	6.7	7.3	8.0	8.7	9.3	10.0	ISO 20696: 2018 (5.5.2)
Effective Length Minimum mm	275	275	275	275	275	275	275	275	ISO 20696: 2018 (5.5.3)
Drainage Lumen Flow rate of Foley Balloon Catheter ml/min	100	100	100	100	100	100	100	100	ISO 20696: 2018 (6.5)
Irrigation Lumen Flow rate of Foley Balloon Catheter ml/min (For Three-way)	25	25	25	30	30	30	NA	NA	ISO 20696: 2018 (6.5)
Test Volume Recovered %	80	80	80	80	80	80	80	80	ISO 20696: 2018 (6.4.2)
Strength of Foley Balloon Catheter	No sign of failure on Tip, Shaft, Eyes								ISO 20696: 2018 (6.1)
Connector Security	Complies								ISO 20696: 2018 (6.2)
Balloon Safety	No leakage from the balloon drainage eye, should not be occluded from the balloon								ISO 20696: 2018 (6.3)
Sterilisation	SAL 10 ⁻⁶ ETO Sterilisation Process validated as per ISO 11135: 2014								EN ISO 11135: 2014
Sterility Test	Should meet the requirements of EN ISO 11737-2								EN ISO 11737-2: 2019

Disclaimer:

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