

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 (Two-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 EN ISO 15223-1: 2021
Shelf Life	5 years from the date of manufacture
Storage Condition	Store in cool, clean & dry condition, away from heat & direct sunlight, Recommended storage condition: 5°C - 40°C
Certifications	CE under EU MDR 2017/745, ISO 13485: 2016
Quality Standard	ISO 20696

Packaging Details

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

Variants

Variants	Sizes
Sterile Foley Balloon Catheter (Two-way)	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr

Device Name	Sterile Foley Balloon Catheter
Catalogue No.	FBC2LE
Device Sizes	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr
Device Variants placed in the Market	Two-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 (Two-way)													Standards	
Surface Test	Should meet the requirements of ISO 20696												ISO 20696: 2018 (5.4)	
Designated Size FG/Ch/Fr	6	8	10	12	14	16	18	20	22	24	26	28	30	ISO 20696: 2018 (5.5.2)
Outside Diameter ± 0.33 (mm)	2.0	2.7	3.3	4.0	4.7	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	150	150	150	275	275	275	275	275	275	275	275	275	275	ISO 20696: 2018 (5.5.3)
Drainage Lumen Flow rate of Foley Balloon Catheter ml/min	10	15	30	50	70	100	100	100	100	100	100	100	100	ISO 20696: 2018 (6.5)
Test Volume Recovered %	55	55	55	80	80	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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