

# 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 U-Drain Male Incontinence Device

### Product Information

The Nulife U-Drain is designed to serve males experiencing urinary incontinence or frequent urination and is also suitable for bedridden patients.

Its straightforward and user-friendly design enables patients to utilise it independently, without the need for expert assistance.



Device Sizes	Ex-Small, Small, Medium, Large, Ex-Large
Device Variants placed in the market	Sterile and Non-Sterile
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.

### Special Features

- Comfortable, easy-to-use, one-piece device
- Snug-fit without constriction
- Individual adhesive strip for proper fixing



# TECHNICAL SPECIFICATION SHEET

## Product Information

<b>Product Name</b>	Male Incontinence Device (U-Drain): sterile & non-sterile
<b>Material</b>	Natural Rubber Latex
<b>Colour</b>	Pale Yellow (colour may vary due to storage time and conditions)
<b>Sterilisation</b>	Sterile (Ethylene Oxide) & N/A for Non-sterile
<b>Labelling</b>	Shall comply with the corresponding labelling specification, customer requirement and EN ISO 15223-1: 2021
<b>Shelf Life</b>	5 years from the date of manufacture
<b>Storage Condition</b>	Store in cool, clean & dry condition, away from heat & direct sunlight. Recommended storage condition 5°C - 40°C
<b>Certifications</b>	CE under EU MDR 2017/745, ISO 13485: 2016

## Variants

Variant	Code
Male Incontinence Device (U-Drain): sterile	UDRLE
Male Incontinence Device (U-Drain): Non-sterile	UDRLN

Variant	Sizes
Male Incontinence Device (U-Drain): sterile	Ex-Small, Small, Medium, Large, Ex-Large
Male Incontinence Device (U-Drain): Non-sterile	Ex-Small, Small, Medium, Large, Ex-Large

## Packaging Details

Pouch	1 pc
Inner Box	50 pcs
Master Carton	600 pcs (12 inner boxes)

## Size Details

Sizes	Total Length	Width	Thickness
Small (S)/Extra Small (XS)	Min 160 mm	35±3 mm	0.08 mm minimum
Medium (M)	Min 160 mm	44±3 mm	0.08 mm minimum
Large (L)/Extra Large (XL)	Min 160 mm	50±3 mm	0.08 mm minimum

Male Incontinence Device (U-Drain) Sterile specification	Standards
The length shall be expressed in millimeters and will be measured from end-to-end, parallel to the axis of the U-Drain	In-House Specification
The flat width of the tube shall be expressed in millimeters and will be measured at a right angle to the axis of the U-Drain	In-House Specification
The thickness of rubber in mm. Minimum: 0.1mm.	In-House Specification
The tensile strength and elongation at break for the U-Drain when tested shall be as under: a) Tensile strength, MPA, Minimum: 18 b) Elongation at break %. Minimum: 700	In-House Specification
The U-Drains or suitable portion of U-Drains, when subjected to accelerated ageing at a temperature of 70±2°C for 168 hours or 100±2°C for 22±0.3 hours, shall have tensile strength and elongation at break as follows: a) Tensile strength after ageing, MPA, Minimum: 15.5 b) Elongation at break after ageing, %, MPA, Minimum: 630 The minimum single-wall thickness shall be measured in millimeters using dial-type gauge. Three random measurements shall be taken along the axis of the U-Drain.	In-House Specification
SAL 10 <sup>-6</sup> ETO Sterilization Process Validated as per ISO 11135: 2014	EN ISO 11135: 2014
Should meet the requirements of EN ISO 11737-2	EN ISO 11737-2: 2019

## Disclaimer:

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