

1. PRODUCT DESCRIPTION

Hypodermic needles are single-use medical devices intended for the hypodermic administrator of pharmaceutical fluids/medicines. Hypodermic needles are manufactured in different sizes, depending on the various exterior diameters and lengths of the cannulas. Each type of needle is recognized by the colour of the hub and by the identification system.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 6, medical device (classification as per MDR Annex II Section 1.1(f); Annex VIII.) 2007/47/EEC)

3. INTENDED USE & PRODUCT CHARACTERISTICS

A hypodermic needle is a hollow needle commonly used with syringe to inject substances into the body or extract blood from the vein.

- The hypodermic needles are completely sterile, ensuring a high level of safety during use.
- Each needle is designed with a plastic luer lock that allows a firm and secure connection with the syringe.
- A plastic protective cap is provided on every needle to maintain hygiene before use.
- The needles are made from non-toxic and pyrogen-free materials, making them safe for patients.
- Colour coding is used according to international standards to clearly identify the needle gauge.

- These needles are intended for single-use only, reducing the risk of cross-contamination.
- Every needle is individually packed in a peel-away pouch to preserve sterility.
- An integrated safety mechanism is included, which can be activated using **one hand** and permanently locks over the needle after use, helping to prevent needle stick injuries.

4. PRODUCT VARIANTS

Following variants are available for the products

S.N	Product	Size (G)	GMDN Code	Classification
1	Hypodermic Needle	16, 17, 18, 19, 20, 21, 22, 23, 24, 26,27	12745	Rule-6, Class-IIa

5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1	Needle Hub	Polypropylene SRM 100 NC
2	Needle	SS 304
3	Needle Cover	Polypropylene SRM 100 NC

6. PRODUCT SPECIFICATION

Gauge	Colour	Needle Diameter (mm)	Length (mm) (±0.05)	Packing Inner/ Outer Unit
16G	White	1.6	44mm & 32mm	100/1000
18G	Pink	1.2	44mm & 32mm	100/1000
19G	Cream	1.10	44mm & 32mm	100/1000
20G	Yellow	0.90	44mm & 32mm	100/1000
21G	Green	0.80	44mm, 39mm & 32mm	100/1000
22G	Black	0.70	44mm, 39mm & 32mm	100/1000
23G	Blue	0.60	44mm, 39mm & 32mm	100/1000
24G	Purple	0.55	44mm, 39mm & 32mm	100/1000
25G	Orange	0.50	44mm, 39mm & 32mm	100/1000
26G	Brown	0.45	45mm, 39mm, 32mm & 20mm	100/1000

7. REFERENCE COMPLIANCE STANDARD

Sr. No.	Title	Standard Ref. No.
1.	Sterile hypodermic needles For Single Use– Requirements and Test Methods.	ISO 7884 -1: 2016
2.	Stainless steel needle tubing for the manufacture of medical devices	ISO 9626 :2016
3.	Hypodermic Needles for Single Use- Colour Coding for Identification	ISO 6009:2016
4.	6% Luer- Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2016
5.	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
6.	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
7.	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
8.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017

9.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
10.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
11.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly Processes	EN ISO 11607-2:2019
12.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2018
13.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
14.	Medical devices – application of risk management to medical Devices	ISO 14971:2019
15.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
16.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL	Quantity
Individual Sterile Packing (Blister)	Soft blister	01 Unit
Inner Carton	400 GSM White Duplex Sheet	100 Unit
Master Carton	5Ply Brown Corrugated Box	10000 Unit

9. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Sector-59, Phase-II, Ballabhgarh, 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: 12745