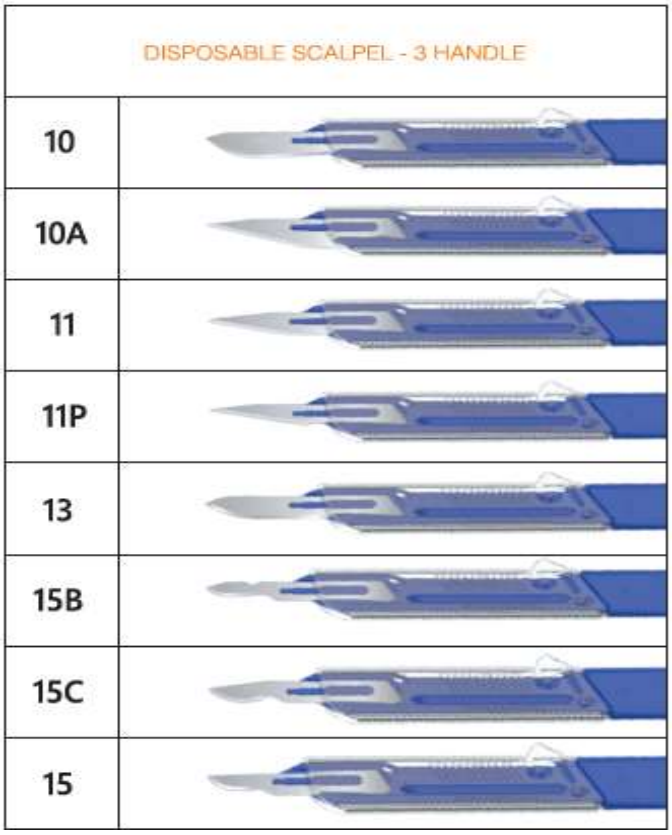


1. PRODUCT DESCRIPTION:

A disposable scalpel is made of plastic handle and a surgical blade made of hardened carbon steel or stainless steel that is fixed to it. Scalpel blades are sterile single use. Duration of Use: Transient Use. Material of Composition: SS/CS, PP, PC.

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.)

3. INTENDED USE:

Intended for tissue Incision and other procedure that require sharp blade to puncture or cut. These are used for surgery.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.NO	Product	Size	GMDN Code	Classification / Rule	Sterilized
1.	Safety Sheath Scalpel	10,10A,11,11P,13,15,15 B,15C	37445	Class-IIa, Rule-6	EO (Ethylene Oxide)

5. MATERIAL OF CONSTRUCTION:

S. No	Component Description	Material used
1	Sheath Handle	ABS
2	Sheath Cover	PC
3	Surgical Blade	SS

6. PRODUCT SPECIFICATION:

- It combines ergonomic design with secure disposal functionality ensuring smooth handling and minimizing the risk of sharp edge injuries post-surgery.
- With the ability to permanently lock the blade by moving the sheath to the lock position, this safety scalpel provided an added layer of protection.
- Plastic handle fitted with Stainless steel blades, allow surgeons to have full view of incision sight while performing Surgery as blade get fully exposed under open position.
- Easy and smooth movement allows Surgeons to use with ease in conducting procedure.

7. REFERENCE COMPLIANCE STANDARD:

S.No.	Harmonized standards	Standard Number
1.	Instruments for surgery — Scalpels with detachable blades — Fitting dimensions	ISO 7740:1985
2.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
3.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
4.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO11607-1:2019/ Amd 1:2023
5.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	ISO11607-2:2019/ Amd 1:2023
6.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
7.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
8.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
9.	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009

10.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
11.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
12.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2021
13.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
14.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
15.	The European Union Medical Device Regulations	MDR 2017/745
16.	Medical devices - Part - 1 : Applications of Usability engineering to the medical devices.	IEC 62366:2015
16.	Clinical Investigations of medical devices for human subjects - Good Clinical Practices	ISO 14155:2020
17.	Medical Devices - Post Market Surveillance for manufacturers	ISO 20416:2020
18.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
19.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,
20.	Sterilization of health care product-Ethylene oxide- Requirement for the Development, validation and routine control for a sterilization process for medical device	EN ISO 11135:2014/And 1:2018
21.	Sterilization of health care products-Chemical indicator-Part 1 General requirement	EN ISO 11140-1:2014
22.	Medical devices-Post market Surveillance for manufacturer	ISO/TR 20416:2020
23.	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
24.	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 11135:2014

8. PACKAGING DETAILS:

Packaging specifications		
1.	Individual pack (Soft Blister)	01 Nos.
2.	Inner Carton (330GSM)	10 Nos.
3.	Outer / Master Carton (5Ply)	1000 Nos.

9. COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabhgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016, TUV SUD Product Service GmbH CE Marking: **TUV SUD Product Service**: GmbH, EC Notified body No. 0123
GMDN Code: 37445

10. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature