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, PP, ABS.

2. DEVICE CLASSIFICATION AND RULE:

The product disposable scalpel is classified under Class IIa/Rule6, as per Medical Device Rule 2017/745.

3. INTENDED USE:

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

Key Feature:

- It is made of plastic handle fitted with SS blade.
- Ergonomical design of scalpel allows smooth handling.
- Fluted finger grip on handle provides easy grip.
- Size of the Blade is marked on the handle for easy visualization.
- Individually packed in a soft Blister.
- Shelf life of 5 years.

4. PRODUCT VARIANTS:

Following variants are available for the products:

S.NO	Product	Type	Gauge/Size	Packing
1.	Sterile disposable scalpel with blade	Stainless Steel	10	Individually packed
2.	Sterile disposable scalpel with blade	Stainless Steel	11	Individually packed
3.	Sterile disposable scalpel with blade	Stainless Steel	12	Individually packed
4.	Sterile disposable scalpel with blade	Stainless Steel	13	Individually packed
5.	Sterile disposable scalpel with blade	Stainless Steel	14	Individually packed
6.	Sterile disposable scalpel with blade	Stainless Steel	15	Individually packed
7.	Sterile disposable scalpel with blade	Stainless Steel	16	Individually packed
8.	Sterile disposable scalpel with blade	Stainless Steel	17	Individually packed
9.	Sterile disposable scalpel with blade	Stainless Steel	18	Individually packed
10.	Sterile disposable scalpel with blade	Stainless Steel	19	Individually packed
11.	Sterile disposable scalpel with blade	Stainless Steel	20	Individually packed
12.	Sterile disposable scalpel with blade	Stainless Steel	21	Individually packed
13.	Sterile disposable scalpel with blade	Stainless Steel	22	Individually packed
14.	Sterile disposable scalpel with blade	Stainless Steel	23	Individually packed
15.	Sterile disposable scalpel with blade	Stainless Steel	24	Individually packed

5. MATERIAL OF CONSTRUCTION:

S.No	Component Description	Material used
1.	Handle	ABS
2.	Blade	Stainless Steel
3.	Cap	Polypropylene

6. REFERENCE COMPLIANCE STANDARD:

S.No.	Name Of Standard	Standards
1.	Instruments for surgery — Scalpels with detachable blades — Fitting dimensions	ISO 7740:1985
2.	Materials and packaging of surgical Scalpels with Detachable with Detachables blades	BS 2982:1992
3.	Sampling Procedure For Inspection By attributes	ISO 2859-1:2026
4.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
5.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by	EN ISO 14644-1:2015
6.	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
7.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018/A1:2021
8.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020/A1:2023
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	EN ISO 11607-2:2020/A11:2022
10.	Sterilization of health care products-Biological indicator-Part 1 General requirement	EN ISO 11138-1:2017
11.	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/A1:2019
12.	Sterilization of health care products-Chemical indicator-Part 1 General requirement	EN ISO 11140-1:2014
13.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2025
14.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
15.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
16.	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009/A11:2025
17.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2023
18.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018

19.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
20.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
21.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
22.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015/Amd 1:2020
23.	Medical Devices - Post Market Surveillance for manufacturers	EN ISO 20416:2020
24.	The European Union Medical Device Regulations	MDR 2017/745
25.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
26.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,
27.	Surgical instruments — Materials Part 1: Metals	ISO 7153-1:2016
28.	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices	ISO 17664-1:2021

7. PACKAGING DETAILS:

Packaging specifications		
1.	Individual pack	01 Nos.
2.	Inner Box	10 Nos.
3.	Outer / Master Carton	1000 Nos.

8. OTHER DETAILS

Storage: Store in a cool and dry place and keep away from direct sunlight and extreme heat.

Method of Sterilization: Sterilized using ethylene oxide.

Shelf life: 05 years from the month / date of sterilization.

Biocompatibility: The product has been evaluated in accordance with ISO 10993-1 and applicable parts of the ISO 10993 series, and complies with the relevant biocompatibility requirements; supporting reports are maintained by Quality Assurance and are available upon request.

Disposal: After single use, dispose of the product in an approved biohazard sharps container or clinical waste bag in accordance with hospital policy and applicable local regulations.

9. COMPLIANCE INFORMATION:

Manufacturer Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, 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