1.0 Product: Disposable Scalpel in stainless steel

1.1 Model/Variant

Trade/ Brand Name	Product Name	Model	Reference No	UDI-DI	EMDN Code
Paramount	Disposable Scalpel	Disposable Scalpel No 9	PDSS9	8903175001198	V010102
		Disposable Scalpel No10	PDSS10	8903175001211	V010102
		Disposable Scalpel No10A	PDSS10A	8903175001235	V010102
		Disposable Scalpel No11	PDSS11	8903175001259	V010102
		Disposable Scalpel No11K	PDSS11K	8903175001273	V010102
		Disposable Scalpel No11P	PDSS11P	8903175000320	V010102
		Disposable Scalpel No12	PDSS12	8903175001297	V010102
		Disposable Scalpel No12D	PDSS12D	8903175090963	V010102
		Disposable Scalpel No13	PDSS13	8903175001310	V010102
		Disposable Scalpel No14	PDSS14	8903175001334	V010102
		Disposable Scalpel No15	PDSS15	8903175001358	V010102
		Disposable Scalpel No15B	PDSS15B	8903175001372	V010102
		Disposable Scalpel No15C	PDSS15C	8903175001396	V010102
		Disposable Scalpel No15D	PDSS15D	8903175000283	V010102
		Disposable Scalpel No15S	PDSS15S	8903175000306	V010102
		Disposable Scalpel No16	PDSS16	8903175001419	V010102
		Disposable Scalpel No17	PDSS17	8903175001433	V010102
		Disposable Scalpel No18	PDSS18	8903175001457	V010102
		Disposable Scalpel No19	PDSS19	8903175001471	V010102
		Disposable Scalpel No 20	PDSS20	8903175001495	V010102
		Disposable Scalpel No 21	PDSS21	8903175001518	V010102
		Disposable Scalpel No22	PDSS22	8903175001532	V010102
		Disposable Scalpel No22A	PDSS22A	8903175001556	V010102
		Disposable Scalpel No 23	PDSS23	8903175001570	V010102
		Disposable Scalpel No 24	PDSS24	8903175001594	V010102
		Disposable Scalpel No 24D	PDSS24D	8903175000344	V010102
		Disposable Scalpel No 25	PDSS25	8903175001617	V010102
		Disposable Scalpel No 26	PDSS26	8903175000528	V010102
		Disposable Scalpel No 34	PDSS34D	8903175000368	V010102
		Disposable Scalpel No 36	PDSS36	8903175001631	V010102
		Disposable Scalpel No 36D	PDSS36D	8903175000382	V010102

1.2 International Product Standards:

1.2 International Standard: ISO 7740: 1985 (EN 27740: 1992): Instruments for Surgery - Scalpels with detachable blades - Fitting dimension.

1.3 International Standard: ISO 7153-1 2016 Surgical instruments —Metallic materials —Part 1: Stainless steel

2.0 Raw Material:

Disposable Scalpel are manufactured from Stainless Steel blade mounted on ABS handle & covered with LDPE cap/sheath. Steel used to produce the blades conforms to the following standards.

2.1 Stainless Steel composition is as defined in ISO 7153-1 2016 (Grade F)

Constituent	**Percent**
Carbon	0.6 to 0.7
Manganese	1.0 max.
Chromium	12.0 to 13.5
Silicon	0.5 max.
Phosphorus	0.03 max.
Sulphur	0.025 max.
Nickel	0.5 max.

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3.0 Outline Shape, Fitment and Nomenclature:

3.1 Outline Shape:

As per Controlled drawings

3.2 Fitment with handle (slot size):

As per ISO 7740: 1985.

3.3 Nomenclature

As per controlled drawings numbers.

4.0 Hardness, Workmanship & Finish

4.1 Hardness

Stainless Steel Disposable Scalpel blades have a minimum hardness of 700 HV on the Vickers Scale.

4.2 Blade Breaking Strength

There is no international specification/standard for breaking strength of the blade. Blades are tested for breaking strength as per company specification which is derived from the comparative data. The strength is different for every blade design.

4.3 Finish

When inspected by normal or corrected vision, blades shall have a smooth finish and shall be free from burrs and corrosion.

Blades are 100 percent visually inspected for -

a) Any bends, (Lack of flatness)
b) Stropping defect. (Burr in cutting edges, bends edges)
c) Polishing deficiency, (Dull finish, un-polished surface)
d) cleaning deficiency, (oil stain, water stain, residuals)
e) Damaged, (handle cut, cutting edge damages, broken)
f) Press marks, (burrs, dents)
g) Surface Defects (Pitting, rust, spot, scratch mark)
h) flash, black spot, short molding

4.4 Grinding defects-

Blades are 100% checked after grinding process for grinding defects like cut uneven, point round, profile defect, burning, no burr, waviness, feather.

4.5 Cutting Edge

The central plane of the cutting edge shall be central with respect to the blade and, cutting angle of the blade should be 16° to 28°.

4.6 Sharpness test

Sharpness of scalpel is checked for each batch by cutting chamois leather.

4.7 Seal test/Dye penetration Test

Five Scalpel are taken from each batch at random from the finished lot and tested for soundness of seal. These Scalpel pouches Inject approx 2 to 5 ml dye penetrant into the package approximately 5mm above sealed area for 5 to 20 seconds. No leakage should appear.

4.8 Seal Strength Test

Two pouches from each batch at random tested for the seal strength as per EN 868 on the calibrated seal strength machine. The seal strength of 15mm specimen pouch should not be less than 1.5N.

4.9 Freedom from foreign matters

Scalpel Blades shall be clean and free from foreign matters when inspected by normal or corrected vision.

5.0 Packaging

5.1 Primary Packaging

Sterile Stainless-Steel Disposable Scalpel are individually packed in medical grade paper with soft blister film.

5.1.1 Material Specification

- GSM of Medical grade paper is (65-75)
- GSM of Soft blister film is (70-80)

5.1.2 Dimension – Nominal

Size of Stainless-Steel Disposable Scalpel packet is given below for fitment 3 & 4.

Fitment- 3: 190 x 33 mm Fitment- 4: 205 x 33 mm

5.2 Inner Box of Disposable Scalpel.

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Ten (10) individually packed Stainless-Steel Disposable Scalpel are contained in one inner box.

5.2.1 Material Specification

Inner boxes are made from ≥ 330 GSM printed paper, 2 side flapped with tear-out dispensing aperture to the bottom right hand corner.

5.2.2 Dimension – Nominal

Inner box dimension: 210 (L) x 70 (W) x 30 (H)

5.3 Export Carton of Disposable Scalpel

Hundred (100) inner boxes are placed in one 5ply Export Carton.

5.3.1 Material Specification

Export cartons are made from 5 ply Top layer duplex/virgin and rest semi craft with total gsm ≥ 730 GSM.

5.3.2 Dimension – Nominal

Export cartons dimension 440 (L) x 370 (W) x 330 (H)

6.0 Labeling and Marking

Labeling and Marking of Disposable Scalpel is fully compliant with the requirements of EN ISO 15223-1:2021, EN 1041.

6.1 Disposable Scalpel Blades

Stainless Steel Disposable Scalpel are stamped with the words “SS along with size “.

6.2 Primary Pouch (Sterile barrier System)

6.2.1 Top Web

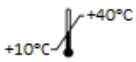
- Product Description
- CE 2460
- Don’t use broken package symbol & Text
- Single use only symbol
- Keep away from heat symbol
- Keep in dry place symbol
- Do not re-sterile symbol
- Storage temperature Symbol
- Method of sterilization symbol
- Dispose in Sharps container symbol
- Packet peel direction
- Punch No if needed
- Manufacture Name & License number
- Medical Device Symbol

6.2.2 Bottom Web

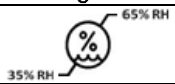
The bottom web is transparent poly film and has no symbols.

6.3

- **Secondary Pack (Inner carton)**: inner carton identifies the following information either preprinted or labeled on it:

I. Sl. No.	Descriptions	Symbol	Sl. No.	Descriptions	Symbol
1	Caution/ Warning (Read IFU before use)		11	Temperature limitation	
2	Product reference/Catalogue No.		12	Do not use if package is damaged	
3	Do Not Reuse		13	Consult for instruction	
4	Lot Number/Batch Number		14	CE Marking	
5	Date of Manufacturing with country of origin		15	Keep away from sunlight	
6	Use By / Expiry Date		16	European Authorized Representative	
7	Sterilized by Gamma Irradiation in conjunction with single barrier sterile system read size		17	Do not re-sterilize	

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8	Manufactured by & Mfg. License no.		**18**	Non-Pyrogenic	
9	Keep dry		**19**	Medical Device	
10	Moisture limitation				

6.4 Tertiary Pack (Export Cartons) Each Export carton bears the information:

- Description of contents
- Consignee details
- Sterile LOT number
- Quantity
- PO No.
- Mfg. License No.
- Total No. Of cases
- Shipping Marks
- Packing List No.
- Material
- Invoice No.
- Manufacturer Name
- Case No. of total No of Cases
- Do not use hook Symbol
- Fragile Symbol
- This side up symbol
- Keep away from water Symbol
- Keep away from direct sunlight

7.0 Sterilization of Disposable Scalpel:

Sterilization by gamma radiation to a minimum dosage of 25 kGy (2.5 Mrads). Sterilization protocol in compliance with ISO 11137-1:2025 and EN 552.

8.0 Shelf life of product

5 years from date of sterilization.

9.0 References

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