

1. PRODUCT DESCRIPTION

Surgical blades are made of Carbon Steel or Stainless Steel. It can be attached to steel scalpel handle. Surgical blades are for single use. Duration of Use: Transient Use.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 6, medical device Rule 2017.

3. PRODUCT CHARACTERISTICS & INTENDED USE

Intended for use as Incision device during surgical, pathological and minor medical procedures.

4. PRODUCT VARIANTS

S. No.	Product	Type	Blade Fitment no. (As per ISO 7740 standard)	Blade number / Size	Classification/ Rule
1.	**Surgical Blade**	Stainless Steel Carbon Steel	3	9,10,10A,10R,11,11P ,11SM,12,12B/12D,1 3,14,15,15SM,15B,1 5C,16,17,18,19	IIa / 6
			4	20,21,22,23,24, 25,26,36,60,70	
2.	**Surgical Blade (with rib)**	Stainless Steel Carbon Steel	3	10,10A,11,11P,11SM ,13,14,15,15SM,15C, 15B,16,17,18,19	IIa/6
			4	20,21,22,23,24,25,36	

Prepared by:	Reviewed by:	Approved by:	Issued by:	
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3.	**Surgical Blade (Fine)**	Stainless Steel	3 no. & 4 no. Not Applicable	61,62,63,64,65,67,69, 90,91	IIa/6
4.	**Surgical Blade (PM)**	Stainless Steel	PM40	40,40B	IIa/6

5. MATERIAL OF CONSTRUCTION CARBON STEEL

S. No.	Component description	Material Used
1.	Surgical Blade	SS Material ISO 7153-1:2016 CS Material as per BS 2982:1992
		Specification for materials and packaging as per BS 2982: 1992

6. PRODUCT SPECIFICATION:

S.No	Blade size	Blade fitment no.	Length	Tolerance	Width	Tolerance
	Commercial number	**As per ISO 7740 standard**	**In mm**	**In mm**	**In mm**	**In mm**
1.	9	3 no.	39.5	± 2.0	10.3	± 0.5
2.	10	3 no.	42	± 2.0	7.5	± 1.0
3.	10A	3 no.	41.5	± 2.0	7.6	± 0.5
4.	11	3 no.	40.91	± 2.0	6.02	± 0.5
5.	11SM	3 no.	40.91	± 2.0	6.02	± 0.5
6.	11P	3 no.	40	± 2.0	6	± 0.5
7.	12	3 no.	38	± 2.0	10.5	± 0.5
8.	12D/12B	3 no.	38	± 2.0	10.5	± 0.5
9.	13	3 no.	41.5	± 2.0	6.1	± 0.5
10.	14	3 no.	46.1	± 2.0	7.4	± 0.5
11.	15	3 no.	37.2	± 2.0	5.6	± 0.5
12.	15B	3.no	39.0	± 2.0	4.0	± 0.5
13.	15SM	3 no.	37.5	± 2.0	5.6	± 0.5
14.	15C	3 no.	38.6	± 2.0	3.9	± 0.5
15.	16	3 no.	46.5	± 2.0	7.1	± 0.5
16.	17	3 no.	38.5	± 2.0	3.3	± 0.5
17.	18	4 no.	54	± 2.0	9.0	± 1.0
18.	19	4 no.	52.2	± 2.0	9.3	± 0.5
19.	20	4 no.	47	± 2.0	9.5	± 0.5

20.	21	4 no.	53.3	± 2.0	9.5	± 0.5
21.	22	4 no.	56.5	± 2.0	10.8	± 0.5
22.	23	4 no.	51.5	± 2.0	9	± 0.5
23.	24	4 no.	55.4	± 2.0	10.27	± 0.5
24.	25	4 no.	51	± 2.0	9.5	± 1.0
25.	26	4 no.	56.5	± 2.0	11	± 1.0
26.	36	4 no.	59	± 2.0	8.8	± 1.0
27.	60	4 no.	67.7	± 2.0	9.8	0.5
28.	70	4 no.	67.7	± 2.0	9.8	0.5
29.	40	N/A	11.4	± 2.0	19	± 0.5
30.	40B	N/A	108.6	± 2.0	19	± 0.5
31.	61	N/A	33	± 1.5	1.6	± 0.1
32.	62	N/A	33	± 1.5	2.5	± 0.1
33.	63	N/A	33	± 1.5	2.2	± 0.2
34.	64	N/A	35.15	± 1.5	2.7	± 0.2
35.	65	N/A	33.8	± 1.5	2.7	± 0.1
36.	67	N/A	33.56	± 1.5	2.3	± 0.2
37.	69	N/A	33.2	± 1.5	2.2	± 0.2
38.	90	N/A	33.9	± 1.5	1.6	± 0.2
39.	91	N/A	33.5	± 1.5	2.0	± 0.2

7. REFERENCE COMPLIANCE STANDARD

S No.	Harmonized standards	Standard Number
1.	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999
2.	Instruments for surgery - Scalpels with detachable blades - Fitting dimensions	ISO 7740 : 1985
3.	Specification for materials and packaging of surgical scalpels with detachable blades	BS 2982 : 1992
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 particle concentration	EN ISO 14644-2:2015
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.	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management	ISO 11607-1:2019/Amd 1:2023

8.	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management	ISO 11607-2:2019/Amd 1:2023
9.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
10.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
11.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
12.	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
13.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
14.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
15.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2021
16.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
17.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
18.	The European Union Medical Device Regulations	MDR 2017/745
19.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
20.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
21.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366: 2015
23.	Clinical Investigations of medical devices for human subjects - Good Clinical Practices	ISO 14155:2020
24.	Medical Devices - Post Market Surveillance for manufacturers	ISO 20416:2020
25.	General Specifications & Validation methods for non-sterile medical device packages in good distribution practice principles	ISO 23417:2020
26.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
27.	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Amendment 2: Revision to 4.3.4 and 11.2	ISO 11137-1:2006/Amd 2:2018

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing	Aluminum Foil
Inner Carton	SBS Board with lamination
Master Carton	5 Ply corrugation

9. OTHER DETAILS

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

Method of Sterilization: sterilized using Gamma Radiation

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

Biocompatibility: the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

Disposal: Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10. COMPLIANCE INFORMATION

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

ABBREVIATIONS

QMS – Quality Management System

GMDN – Global Medical Device Nomenclature