

	PARAMOUNT SURGIMED LIMITED		Doc. No.: PSL/TDS02 Rev. No.: 00
	TECHNICAL DATA SHEET		Page No. 1 of 4
Name of Product	Disposable Scalpel		
Reference No.	02	Cust. Reference No.	N/A


Name of the company: Paramount Surgimed Limited

Company address: A-106, RIICO Industrial Area, Phase I Bhiwadi
301019 (Raj)-India

Approval of Technical Data Sheet

	Name	Designation	Signature
Prepared By	Ajay Dhasmana	QA(Mgr.)	

	Name	Designation	Signature
Approved By	Rajesh Sabikhi	Sr. GM	

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Technical Data Sheet

Product Name: Disposable Scalpel

Classification:

Class IIa as per rule -6 Annex IX of MDD 93/42/EC with 2007/47/EC Council Directive of 14th June 1993 concerning medical devices.

Description:

The device is used for incision during surgery it is made of Stainless steel (Grade-F) mounted on ABS SD-0150 WK NP-17MT handles and protected by LDPE 16 MA 400 guard. It is supplied sterile conditions. The sterilization process is carried out by/through Gamma irradiation. The product shelf life is 5 years of date of sterilization. The device is packed into blister pouch packing which confirms the medical grade requirements.


Intended Use:

The device is used for incision during surgery. The device is surgically invasive device and for transient use.

Material:


SN	Name of Component	Material	Grade
1	Blade	Carbon and Stainless Steel	Grade- F
2	Handle	ABS	SD0150 WK NP-17MT
3	Protective Cap	LDPE	16 MA 400

Color: Blue handle
Manufacturer: Paramount Surgimed Limited
Country of origin: India

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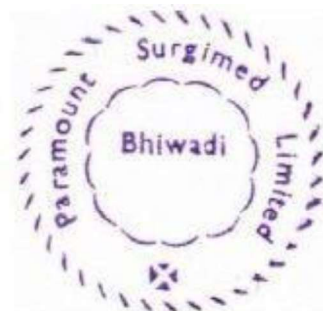
Specification:

SN	Blade Size	Carbon Steel	Stainless Steel	Handle Drawing No.	Cap Drawing No.
		Blade Drawing No.	Blade Drawing No.		
1.	1	PDCS 1	PDSS 1	PSL/DS/3A PSL/DS/3B PSL/DS/3C PSL/DS/3D	PSL/DS/3A/G PSL/DS/3B/G PSL/DS/3C/G PSL/DS/3D/G PSL/DS/3D/12G (For size-12)
2.	2	PDCS 2	PDSS 2		
3.	3	PDCS 3	PDSS 3		
4.	4	PDCS 4	PDSS 4		
5.	5	PDCS 5	PDSS 5		
6.	6	PDCS 6	PDSS 6		
7.	7	PDCS 7	PDSS 7		
8.	8	PDCS 8	PDSS 8		
9.	9	PDCS 9	PDSS 9		
10.	10	PDCS 10	PDSS 10		
11.	10A	PDCS 10A	PDSS 10A		
12.	11	PDCS 11	PDSS 11		
13.	11K	PDCS 11K	PDSS 11K		
14.	12	PDCS 12	PDSS 12		
15.	13	PDCS 13	PDSS 13		
16.	14	PDCS 14	PDSS 14		
17.	15	PDCS 15	PDSS 15		
18.	15B	PDCS 15B	PDSS 15B		
19.	15C	PDCS 15C	PDSS 15C		
20.	15D	PDCS 15D	PDSS 15D		
21.	15S	PDCS 15S	PDSS 15S		
22.	16	PDCS 16	PDSS 16	PSL/DS/4A PSL/DS/4B PSL/DS/4C PSL/DS/4D	PSL/DS/4A/G PSL/DS/4B/G PSL/DS/4C/G PSL/DS/4D/G PSL/DS/4D/22G (For Size-22 & 36)
23.	17	PDCS 17	PDSS 17		
24.	18	PDCS 18	PDSS 18		
25.	19	PDCS 19	PDSS 19		
26.	20	PDCS 20	PDSS 20		
27.	21	PDCS 21	PDSS 21		
28.	22	PDCS 22	PDSS 22		
29.	22A	PDCS 22A	PDSS 22A		
30.	23	PDCS 23	PDSS 23		
31.	24	PDCS 24	PDSS 24		
32.	25	PDCS 25	PDSS 25		
33.	36	PDCS 36	PDSS 36		

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Storage and Disposal:

- (1) Keep away from direct sun light.
- (2) Keep away from rain
- (3) Storage temperature should be 10 to 40 degree Celsius
- (4) Humidity of storage area should be 35% RH to 65 % RH.
- (5) Keep away from children.
- (6) Store in cool and dry place.
- (7) Hand and dispose of contaminated products with care and in accordance with national regulations.



Signature and Stamp