

1. PRODUCT DESCRIPTION:

Dermal curette is made of plastic handle fixed with a circular ring sharp blade. It is a single use device. Duration of Use: Transient Use. Material of Composition: SS, ABS.

2. DEVICE CLASSIFICATION AND RULE:

Dermal Curette falls under Class-IIa (Rule 6) device as per EU MDR 2017/745 Annexure VIII.

3. PRODUCT CHARACTERISTICS & INTENDED USE:

A dermal curette is a surgical instrument designed for scraping or debriding biological tissue or debris in a biopsy, excision, or cleaning procedure.

4. PRODUCT VARIANTS:

S. No.	Product	Type	Size	GMDN	Classification
1.	**Dermal Curette**	Stainless Steel	2.0mm, 3.0mm, 4.0mm, 5.0mm, 6.0mm, 7.0mm, 8.0mm.	35289	IIa/6

5. MATERIAL OF CONSTRUCTION:

S. No.	Component description	Material used
1.	Dermal Curette	AISI- 304
2.	Dermal curette Handle	ABS
3.	Cap	LLDPE/PP

6. TECHNICAL SPECIFICATION:

S.No.	Parameter	Specification	Inspection mode / equipment
1.	ID and OD of tube	As per size of tube	Vernier caliper & micrometer
2.	Thickness	0.20 (±0.025mm)	micrometer
3.	Angle of cutting edge	8° to 10°	Profile projector
4.	Nick, Feathered edges	No nick, feathered edges allowed	visual
5.	Jag	No jag edge allowed	visual
6.	Burr/Scratch	Free from Scratched and Burr	visual

		edge	
7.	Burning	Free from any burn marks	visual
8.	Profile	Profile of dermal curette should be regular and equal from both side	visual
9.	Waviness	No waviness allowed on edge	visual
10.	Sharpness	Each sample tube should cut on surface of leather when put pressure with twist on it	Chamois leather
11.	Corrosion /rust/spot/stains	Dermal curette should be free from corrosion	visual
12.	Oil or grease mark	Dermal curette should be free oil or grease mark	visual
13.	Cap fitting	Easy to insert and should not fall by shaking	visual
14.	Surface finish of handle and cap	Free from extra material, sharp edge and dust particle	visual
15.	Handle and cap color	As per approved artwork	visual

7. REFERENCE COMPLIANCE STANDARD:

S.No	Harmonized standards	Standard Number
1.	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999/ And 1:2011 ISO 2500-1:2000
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.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
8.	Packaging for terminally sterilized medical devices - Part 1:	EN ISO 11607-1:2019

	Requirements for materials, sterile barrier systems and packaging systems	
9.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	EN ISO 11607-2:2019
10.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
11.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
12.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
13.	Biological evaluation of medical devices — Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009
14.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2021
15.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
16.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10993-12:2021
17.	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
18.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
19.	The European Union Medical Device Regulations	MDR 2017/745
20.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
22.	Medical devices - Part - 1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015
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.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
26.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,

27.	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
28.	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	TYPE OF MATERIAL	PACKAGING
Primary Packaging	Soft Blister	01
Secondary Packaging (Inner Carton)	SGS Board	10
Tertiary Packaging (Master Carton)	5 Ply	1000

9. OTHER DETAILS

a. **Intended Use:** refer the instruction for use before the application.
b. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.
c. **Method of Sterilization:** sterilized using ethylene oxide.
d. **Shelf life:** 05 years from the month / date of sterilization.
e. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (Visual Checking, Moulding defect, Packaging Condition, Corrosion, Sharpness, sealing etc) is performed on each batch before release.
f. **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.
g. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10.COMPLIANCE INFORMATION

Manufacturing Site 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
CE Marking: TUV-SUD Product Services GmbH 0123
GMDN: 35289