DEVICE TECHNICAL DATA SHEET

Doc. No. 7D6-1 Rev. No : 02 Rev. Date :25-06-2021

A DEVICE SPECIFICATION

1.	**Device Code**	37-100-20
2.	**Device Name**	Thumb Dressing Forceps
3.	**Device Size**	200 mm
4.	**Device Weight**	45± 5 gm.
5.	**Device Finish**	Satin
6.	**Device Marking**	▪ Device shall be stamped CE ▪ Name / Logo if required by the Customer.
7.	**Device Drawing**	See Attached Drawing
8.	**Intended Use**	Device shall be used for holding purposes.
9.	**Function/Attributes**	Mostly used to hold cotton, gauze and proper tension.
10.	**Risk Classification**	Class I
11.	**Sterilization Method**	Steam (Moist Heat) Sterilization.
12.	**Sterilization Cycles**	Repeated processing has minimal effect on the instrument life. End of useful life for metal surgical instruments is normally determined by wear and damage due to the intended surgical use.

B MATERIAL SPECIFICATION

1.	**Material Used**	AISI 410 Stainless Steel						
2.	**Material Composition**	**C**	**SI**	**MN**	**P**	**S**	**NI**	**CR**
		0.09 to 0.15	Max 1.00	Max 1.00	Max 0.040	Max 0.030	8.00 t 1.00	11.50 to 13.50
3.	**Required Hardness**	41 to 45 HRC						

C COMPONENT SPECIFICATION

1.	**Components Used**	2 Components						
2.	**Component Material**	AISI 410 Stainless Steel						
3.	**Material Composition**	**C**	**SI**	**MN**	**P**	**S**	**NI**	**CR**
		0.09 to 0.15	Max 1.00	Max 1.00	Max 0.040	Max 0.030	8.00 t 1.00	11.50 to 13.50

D PACKAGING SPECIFICATION

1.	**Primary Packaging**	Polyethylene Bag Is Used For Primary Packaging.
2.	**Secondary Packaging**	Paper Board Box In Used For Secondary Packaging.
3.	**Tertiary Packaging**	Card Board Box Is Used For Tertiary Packaging.

E LIST OF APPLICABLE STANDARDS

1.	**ISO 9001:2015**	Quality Management Systems – Requirements
2.	**ISO 13485: 2016**	Medical devices-Quality management systems-Requirements for regulatory purposes.
3.	**ISO 14971:2012**	Medical devices-Application of risk management to medical Devices
4.	**ISO 17665-1:2006**	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
5.	**ISO 15223-1:2016**	Medical Devices –Symbols to be used with medical device labels, labeling and information to be supplied part-1 –general requirements
6.	**cGMP**	Current Good Manufacturing Practice
7.	**MDD 93/42/EEC as updated 2007/47/EC**	Council Directive for Medical Devices
8.	**ASTM F899-12**	Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments
9.	**ISO 7153-1:2016**	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel

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