DEVICE TECHNICAL DATA SHEET

Doc. No. 7D6-1 Rev. No : 03 Rev. Date :22-03-2023

A	DEVICE SPECIFICATION	
1.	Device Code	37-110-16
2.	Device Name	Forceps Sharp Point Str
3.	Device Size	160 mm
4.	Device Weight	25± 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	3 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 14971:2019	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 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
6.	cGMP	Current Good Manufacturing Practice
7.	REGULATION (EU) 2017/745	European Union regulation for Medical Devices
8.	ASTM F899-20	Standard Specification for Wrought Stainless Steels for Surgical Instruments
9.	ISO 7153-1:2016	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel

Prepared By: _____ Approved By: _____

& Date Asad Ashraf (Assistant QA Manager) & Date Tariq Tufail (QA Manager)