



DEVICE TECHNICAL DATA SHEET

Doc. No. 7D6-1 Rev. No : 01 Rev. Date :26-02-2020

A. DEVICE SPECIFICATION								
1.	Device Code	37-110-14						
2.	Device Name	Sharp Point Forceps						
3.	Device Size	140 mm						
4.	Device Weight	23 ± 3 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						
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 0.04	Max 0.030	8.00 to 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 0.04	Max 0.030	8.00 to 1.00	11.50 to 13.50
D. LIST OF APPLICABLE STANDARDS								
1.	ISO 13485	Medical Devices-Quality Management Systems-Requirements for Regulatory Purpose						
2.	ISO 9001	Quality Management Systems						
3.	ISO 14971	Medical Devices-Application of Risk Management to Medical Devices						
4.	ISO 17665	Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of re-sterilizable medical devices						
5.	ISO 15223-1	Graphical Symbols for Use in the Labeling of Medical Devices						
6.	cGMP	Current Good Manufacturing Practice						
7.	MDD 93/42/EEC	Council Directive for Medical Devices						
8.	ASTM-F899	Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments						
9.	ISO 7153-1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel						

Prepared By: _____
& Date

17-8-20

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& Date

17/8/2020