



DEVICE TECHNICAL DATA SHEET

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

A DEVICE SPECIFICATION

1.	Device Code	37-010-14
2.	Device Name	Anatomic Scissors SH / BH Str
3.	Device Size	140 mm
4.	Device Weight	45 ± 5 gm.
5.	Device Finish	Satin
6.	Device Marking	<ul style="list-style-type: none">Device shall be stamped CEName / Logo if required by the Customer.
7.	Device Drawing	See Attached Drawing
8.	Intended Use	Device shall be used for cutting purposes.
9.	Function/Attributes	Mostly used to cut gauze thread, work smoothly and easy grip.
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 420 Stainless Steel						
2.	Material Composition	C	SI	MN	P	S	NI	CR
		0.16 to 0.25	Max 1.00	Max 1.00	Max 0.040	Max 0.030	1.00	12.00 to 14.00
3.	Required Hardness	46 to 50 HRC						

C COMPONENT SPECIFICATION

1.	Components Used	3 Components						
2.	Component Material	AISI 420 Stainless Steel						
3.	Material Composition	C	SI	MN	P	S	NI	CR
		0.16 to 0.25	Max 1.00	Max 1.00	Max 0.040	Max 0.030	1.00	12.00 to 14.00

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.	EU MDR 2017/745	European Union regulation 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

Prepared By: Asad Ashraf
& Date: _____
Asad Ashraf (Assistant QA Manager)

Approved By: Tariq Tufail
& Date: _____
Tariq Tufail (QA Manager)

