

## **DEVICE TECHNICAL DATA SHEET**

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

A	DEVICE SPECI					1907 1907 1008	Manager Street				
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 ■ Device shall be stamped C€										
		Name / 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 sur	gical use.								
В	MATERIAL SP	ECIFICAT	ION	100	Th.						
1.	Material Used	AISI 420 Stai	nless Steel								
•	Material Composition	С	SI	MN	P	S	NI	CR			
2.		0.16 to 0.25	Max 1.00	Max 1.00	Max 0.040	Max 0.030	1.00	12.00 to 14.0			
3.	Required Hardness	46 to 50 HR									
С	COMPONENT	SPECIFIC	ATION								
1.	Components Used	3 Components									
2.	Component Material	AISI 420 Stainless Steel									
_	Material Composition	С	SI	MN	P	S	NI	CR			
3.		0.16 to 0.25	Max 1.00	Max 1.00	Max 0.040	Max 0.030	1.00	12.00 to 14.0			
D	PACKAGING S	SPECIFICA	TION					324			
1.	Primary Packaging										
2.	i i iiiiai y i ackabiiib	Polyethylen	P Raσ Is I Ise	d For Prima	Polyethylene Bag Is Used For Primary Packaging.  Paper Board Box In Used For Secondary Packaging.						
	Secondary Packaging				<u> </u>						
3	Secondary Packaging	Paper Board	Box In Used	d For Secon	dary Packag						
3. F	Tertiary Packaging	Paper Board Card Board I	Box In Used	d For Secon For Tertiary	dary Packag						
		Paper Board Card Board I	Box In Used Box Is Used TANDAR	d For Second For Tertiary <b>DS</b>	dary Packag Packaging.						
E 1.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015	Paper Board Card Board I ICABLE ST Quality Man	Box In Used Box Is Used FANDAR Lagement Sy	d For Second For Tertiary <b>DS</b> estems – Rec	dary Packag Packaging. quirements	ing.	s for regu	latory			
E	Tertiary Packaging  LIST OF APPL	Paper Board Card Board I ICABLE ST Quality Man	Box In Used Box Is Used FANDAR Lagement Sy	d For Second For Tertiary <b>DS</b> estems – Rec	dary Packag Packaging. quirements		s for regu	latory			
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1. 2. 3.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015  ISO 13485: 2016	Paper Board Card Board I ICABLE ST Quality Man Medical dev purposes. Medical dev Sterilization	Box In Used Box Is Used CANDAR Lagement Sylices-Quality Lices-Application	DS rstems – Recommendation of risk are products	packaging. Packaging. Quirements Packaging.  quirements Packaging.  quirements Packaging.	Requirement nt to medical eat — Part 1:	Devices Requirem	ents for the			
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1. 2. 3.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015  ISO 13485: 2016  ISO 14971:2012  ISO 17665-1:2006	Paper Board Card Board ICABLE ST Quality Man Medical dev purposes. Medical dev Sterilization developmer devices	Box In Used Box Is Used TANDAR Lagement Sylices-Quality Lices-Application of health cant, validation	DS  stems – Reconnection of risk and routin	packaging.  Packaging.  quirements  ent systems-  managemer  s — Moist he  e control of	Requirement nt to medical eat — Part 1: a sterilization	Devices Requirem n process	ents for the for medical			
1. 2. 3.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015  ISO 13485: 2016  ISO 14971:2012	Paper Board Card Board I CABLE ST Quality Man Medical dev purposes. Medical dev Sterilization developmer devices Medical Dev	Box In Used Box Is Used FANDAR Lagement Sylices-Quality Lices-Application of health cant, validation	DS  rstems – Recommendation of risk are products and routing to be use	packaging.	Requirement to medical eat — Part 1: a sterilization	Devices Requirem n process	ents for the for medical			
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1. 2. 3. 4. 5.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015  ISO 13485: 2016  ISO 14971:2012  ISO 17665-1:2006  ISO 15223-1:2016  cGMP	Paper Board Card Board Card Board ICABLE ST Quality Man Medical dev purposes. Medical dev Sterilization developmer devices Medical Dev information Current Goo	Box In Used Box Is Used FANDAR Lagement Sylices-Quality Lices-Application of health cant, validation vices —Symbot be suppled Manufact	DS  stems – Recommendation of risk and routing part-1 – curing Practi	dary Packag Packaging. Packaging. Quirements ent systems- managemer s — Moist he e control of ed with med general require	Requirement  It to medical eat — Part 1: a sterilization lical device la uirements	Devices Requirem n process	ents for the for medical			
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1. 2. 3. 4. 5. 6. 7.	Tertiary Packaging  LIST OF APPL  ISO 9001:2015  ISO 13485: 2016  ISO 14971:2012  ISO 17665-1:2006  ISO 15223-1:2016  cGMP  EU MDR 2017/745	Paper Board Card Board Card Board ICABLE ST Quality Man Medical dev purposes. Medical dev Sterilization developmer devices Medical Dev information Current Good European U Standard Sp Instruments	Box In Used Box Is Used FANDAR Lagement Sylices-Quality Lices-Application of health cant, validation Lices -Symbolic to be suppled Manufact Lices in Figure 1 in Figure 1 in Figure 2 in F	DS  stems – Red management  ation of risk are products and routin  ols to be use ied part-1 – curing Practic ion for Med or Stainless	packaging.	Requirement  Int to medical eat — Part 1: a sterilization lical device la uirements	Devices Requirem n process bels, labe	ents for the for medical ling and			

Asad Ashraf (Assistant QA Manager)

Approved By: & Date

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