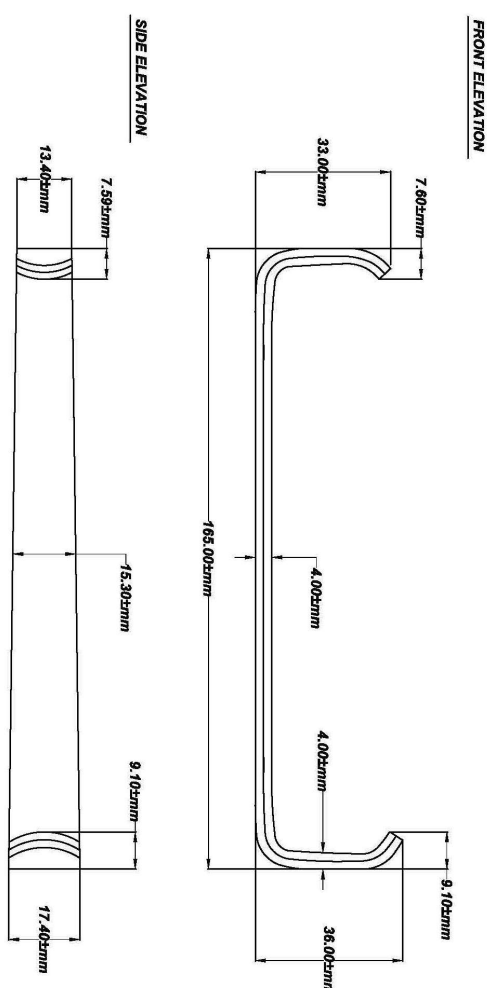

	TATA SURGICAL (PVT) LTD. Mughal Street, Muhammad Pura, Commissioner Road, Sialkot-51310 Pakistan Tel: 0092 52 4580 421 / 22 Fax: 0092 52 459 29 09	Technical documentation Raw material & Set component Rev : 00/05.01.2024 PAGE: 1/4
	Product Data Raw Material / Set Component Item # TABT 0377/1	Sterile: <input type="checkbox"/> Non sterile <input checked="" type="checkbox"/>

Revision	Date	Description of change
00	JAN 2024	Up to date and completion of product data

I- Product Description & Classification			
I/1	Name:	LANE WOUND RETRACTOR	
I/2	General description:	LANE WOUND RETRACTOR SET OF 2 16X33 12X32 16X29 12X27 16.5CM Stainless Steel	
I/3	Classification - Rule:	Class IIa (non-sterile), according to Rule 6 Annex IX of Directive 93/42/EEC Justification: Surgically Invasive, transient use, Single use	
I/4	Drawing:	 <p>SIDE ELEVATION</p> <p>13.40mm, 7.59mm, 15.30mm, 9.10mm, 17.40mm</p> <p>FRONT ELEVATION</p> <p>33.00mm, 7.60mm, 165.00mm, 4.00mm, 4.00mm, 36.00mm, 9.10mm</p>	
I/5	Design:	Dimensions of device : Primary packaging: Shipping packaging: carton	Please see above Zipper Polyethylene Bag Carton Dimensions: 11"x7.50"x7"

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	Product Data Raw Material / Set Component Item # TABT 0377/1	Sterile: <input type="checkbox"/> Non sterile <input checked="" type="checkbox"/>

II- Description of use and operating of device		
II/1	Application/ Intended Use:	Separate the edges of a surgical incision or wound
III- Composition		
III/1	Raw materials:	Stainless steel AISI 410
		Ref. Standards ASTM F899-11 & ISO 7153-1
III/2	INSPECTION AND TESTING <u>Forging of Retractor :</u> Forging of the Retractor is checked keeping in view the following check points: Size of the Retractor is correct and according to the Master Sample/ drawing Pattern/ shape of the Retractor is according to the master sample/ drawing There is no crack, breakage cavities. <u>Filed Retractor :</u> After completion of grinding/ filing processes each filed Retractor is inspected keeping in view the following check points: Size of the Retractor is correct and according to the Master Sample/ drawing Pattern/ shape of the Retractor is according to the master sample/ drawing There is no crack, breakage cavities. The thickness of the Retractor is even and according to Master Sample/Drawing. Milling/machine and assembling of the Retractor is up to the mark. <u>Polished Retractor :</u> After completion of polishing processes the polished Retractor are inspected keeping in view the following check points: Size of the Retractor is correct and according to the Master Sample./Drawing Pattern/ shape of the devices is according to the master sample/ Drawing There is no crack, breakage cavities. Polishing/ finish of the devices is up to the mark and according to instruction of the customer <u>Finished Retractor :</u> Visual inspection and function test: Each finished product is tested for its function and inspected keeping in view the following check points: Function test of the Retractor is performed All parts of the instrument are checked for any extra sharpness which may injure to user and are patient. There should no such sharpness The Retractor are checked visually for foreign materials and there should no extra oil, lint, dust/ polishing compound, scratches, pits The Retractor are checked that these bear the required stamps/label, which are properly set and are legible. Lab Tests: Boil Test on one piece from each lot is performed to check corrosion resistant properties in the material used according to Standard ASTM F 1089-10 One piece from each shipment is tested for proper chemical composition of the stainless steel material used by Sialkot Material Laboratory established by Trade Development Authority of Pakistan, Ministry of Commerce, Government of Pakistan.	
III/3	Average weight of device:	Approximate: 55GRAM



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Product Data

Raw Material / Set Component

Item # TABT 0377/1

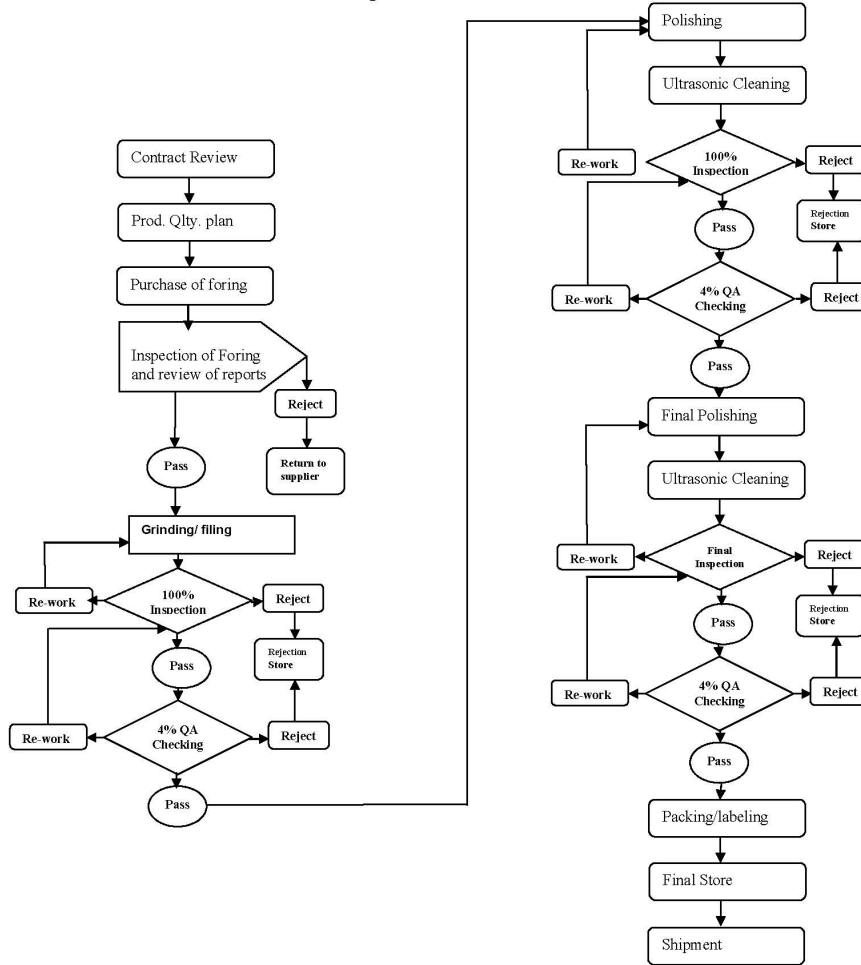
Sterile: ☐


Non sterile: ☒



IV- Methods of manufacturing

IV/1

Manufacturing Method /Process Flow Chart



	TATA SURGICAL (PVT) LTD. Mughal Street, Muhammad Pura, Commissioner Road, Sialkot-51310 Pakistan Tel: 0092 52 4580 421 / 22 Fax: 0092 52 459 29 09	Technical documentation Raw material & Set component Rev : 00/05.01.2024 PAGE: 4/4
	Product Data Raw Material / Set Component Item # TABT 0377/1	Sterile: <input type="checkbox"/> Non sterile <input checked="" type="checkbox"/>

IV/2	Primary packaging:	Bag: Pieces/Bag:	25 Pieces
IV/4	Shipment packaging:	Carton: Bags/Carton	10 Bags
IV/5	<u>Labelling: According to Directive 93/42 CEE Annex I § 13.3</u> <ul style="list-style-type: none"> Name and address of manufacturer : Name /description of product: Article no: Quantity : LOT no : Indication for single use: CE: symbol Other symbol as defined in EN 15223-1 		
	<p>Example of a label for product to be attached to primary packaging</p> <div style="text-align: center;"> Tata Surgical (PVT) Limited <div style="border: 1px solid black; padding: 2px; display: inline-block;">REF</div> TABT 0377/1 LANE WOUND RETRACTOR SET OF 2 16X33 12X32 16X29 12X27 16.5CM Stainless Steel </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>Description</p> <p>Quantity</p>  <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center; margin: 5px;">P</div> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center; margin: 5px;">2</div>  </div> <div style="width: 50%;"> <p>Non-sterile Single Use surgical instruments 25 Pieces The instruments must be store in dry place</p> <p>Only qualified person should use the healthcare devices</p> <p>- This is a disposable product and designed for SINGLE USE DEVICES (SUDs) - Do not Reuse</p> <p>Tata Surgical (Pvt) Ltd, Mughal Street, Muhammad Pura, Commissioner Road Sialkot-Pakistan. Tel: 052 4580 421 / 22, Fax: 052 459 29 09 E-Mail: info@tata.com.pk</p> <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="font-size: 2em; margin-right: 10px;">CE</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-right: 10px;">LOT</div> Lot Number: </div> </div> </div> <div style="margin-top: 10px;"> <p>Operating Instructions :</p> <ul style="list-style-type: none"> - Wear Gloves while using the instruments - Be careful of the sharp point of the instruments, if any - Be careful of the moving parts of the instruments. - Do not re-use. - The instruments must be stored in dry place and must be handled with care to prevent damage - Only qualified person should use the healthcare devices. - Use only for its intended purpose to ensure maximum effectiveness. - After use the instruments should be disposed off According to local laws. </div>		
IV/6	Environment	Harmless	

Tata Surgical (Pvt) Ltd.

 
Director