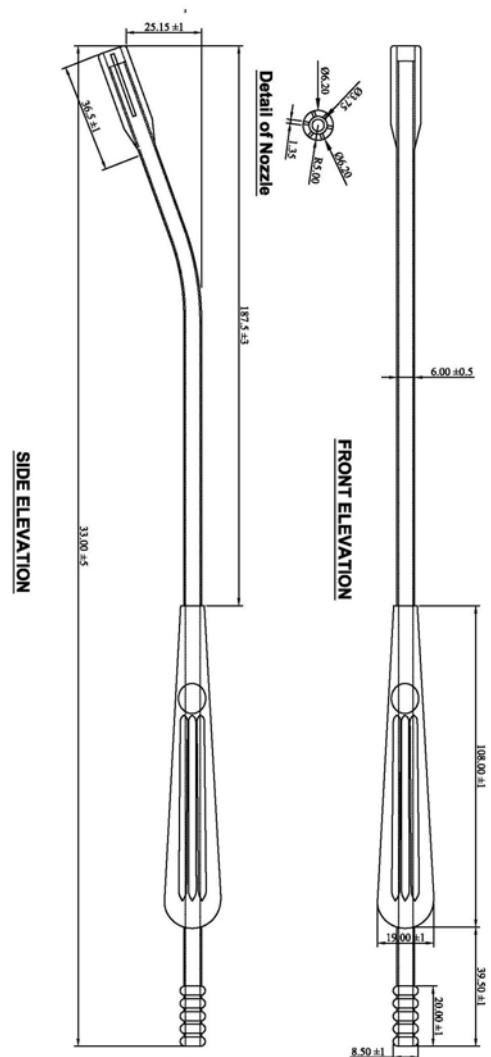
	<p><b>TATA SURGICAL (PVT) LTD.</b>  Mughal Street,  Muhammad Pura, Commissioner Road,  Sialkot -51310 PAKISTAN  Tel: 0092 52 4580 421 / 22  Fax: 0092 52 459 29 09</p> <p><b>Product Data</b>  Raw Material / Set Component  Item # TAYT 10-205 PHW</p>	<p>Technical documentation  Raw material &amp; Set component  Rev :1 /01.08.2023</p> <p>PAGE: 1/4</p> <p><b>Sterile:</b> <input type="checkbox"/>  <b>Non sterile</b> <input checked="" type="checkbox"/></p>
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Revision	Date	Description of change
1	Aug 01,2023	Up to date and completion of product data

**I- Product Description & Classification**

I/1	Name:	YANKAUER SUCTION TUBE, WITH PLASTIC HANDLE
I/2	General description:	YANKAUER SUCTION TUBE WITH PLASTIC ROUND HANDLE 33CM, 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><b>Technical Drawing Details:</b></p> <ul style="list-style-type: none"> <li><b>Side Elevation:</b> Total length 33.00 ± 0.5 mm. Nozzle tip to handle start 18.7 ± 0.3 mm. Nozzle tip to handle start 25.15 ± 0.1 mm. Nozzle tip to handle start 30.5 ± 0.1 mm.</li> <li><b>Front Elevation:</b> Total length 108.00 ± 0.1 mm. Nozzle tip to handle start 6.00 ± 0.3 mm. Nozzle tip to handle start 19.00 ± 0.1 mm. Nozzle tip to handle start 39.50 ± 0.1 mm. Nozzle tip to handle start 20.00 ± 0.1 mm. Nozzle tip to handle start 8.50 ± 0.1 mm.</li> <li><b>Detail of Nozzle:</b> Nozzle tip to handle start 0.125 mm. Nozzle tip to handle start 0.20 mm. Nozzle tip to handle start 0.135 mm. Nozzle tip to handle start 0.10 mm.</li> </ul>	
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I/5	Design:	Dimensions of device :	Please see above
		Primary packaging:	Zipper Polyethylene Bag
		Shipping packaging: carton	Carton Dimensions: 11"x7.50"x7"

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	<b>Product Data</b> Raw Material / Set Component Item # TAYT 10-205 PHW	<b>Sterile:</b> <input type="checkbox"/> <b>Non sterile</b> <input checked="" type="checkbox"/>

II- Description of use and operating of device			
II/1	Application/ Intended Use:	Use for suction of the body fluid in combination with aspirator during operation on thoracic cavity or abdominal cavity.	
III- Composition			
III/1	Raw materials:	HANDLE	PLASTIC
		YANKAUER SUCTION TUBE	Stainless steel AISI 304
		Ref. Standards	ASTM F899-11 & ISO 7153-1
III/2	INSPECTION AND TESTING		
<u>Machined parts :</u> The parts of the instrument are checked after machining keeping in view the following check points: Size of the part is correct and according to the Master Sample/ drawing Pattern/ shape of the part is according to the master sample/ drawing There is no crack, breakage cavities.			
<u>Assembled devices :</u> After completion of assembling processes each assembled device is inspected keeping in view the following check points: Size of the device 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. The thickness of each part of the device is even and according to Master Sample/Drawing.			
<u>Polished devices :</u> After completion of polishing processes the polished Devices are inspected keeping in view the following check points: Size of the devices is correct and according to the Master Sample/Drawing Pattern/ shape of the devices is according to the master sample/ Drawing Sharpness of the tip of the needle is perfect 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 devices :</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 devices is performed. Sharpness of the tip of the needle is perfect There is no crack, breakage cavities Polishing/ finish of the devices is up to the mark and according to instruction of the customer The devices are checked visually for foreign materials and there should no lint, dust/ polishing compound, scratches, pits The devices 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: 98 grams	



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Technical documentation  
 Raw material & Set component  
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## Product Data

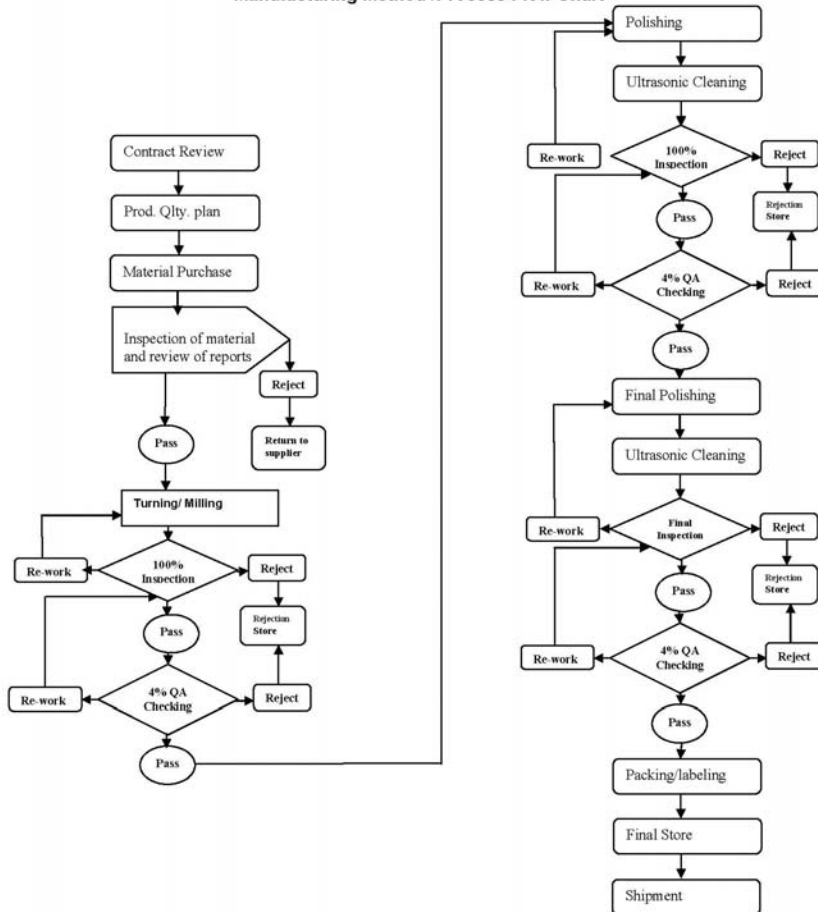
Raw Material / Set Component  
 Item # TAYT 10-205 PHW


Sterile: ☐  
 Non sterile: ☒







### IV- Methods of manufacturing

IV/1

Manufacturing Method /Process Flow Chart



	<b>TATA SURGICAL (PVT) LTD.</b> 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 :1 /01.08.2023  PAGE: 4/4
	<b>Product Data</b> Raw Material / Set Component Item # TAYT 10-205 PHW	<b>Sterile:</b> <input type="checkbox"/> <b>Non sterile</b> <input checked="" type="checkbox"/>

IV/2	Primary packaging:	Bag: Pieces/Bag:	25 Pieces
IV/4	Shipment packaging:	Carton: Bags/Carton	40 Bags
IV/5	<u>Labelling: According to Directive 93/42 CEE Annex I § 13.3</u> <ul style="list-style-type: none"><li>Name and address of manufacturer :</li><li>Name /description of product:</li><li>Article no:</li><li>Quantity :</li><li>LOT no :</li><li>Indication for single use:</li><li>CE: symbol</li><li>Other symbol as defined in EN 15223-1</li></ul>		<p>Example of a label for product to be attached to primary packaging</p> <div><div><div> Description</div><div> Quantity</div><div> Single Use</div><div> Do not Reuse</div><div> Operating Instructions :</div></div><div><div><p><b>Tata Surgical (PVT) Limited</b></p><p><b>TAYT 10-205PHW</b></p><p><b>YANKAUER SUCTION TUBE ROUND PLASTIC HANDLE 33CM, STAINLESS STEEL</b></p><p><b>Non-sterile Single Use surgical instruments</b></p><p><b>25 Pieces</b></p><p>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)</p><p>- <b>Do not Reuse</b></p><p>Tata Surgical (Pvt) Ltd, Mughal Street, Muhammad Pura, Commissioner Road, Sukkot Pakistan. Tel: 032 4580 421 / 22, Fax: 032 459 29 09 E-Mail: info@tata.com.pk</p></div><div><div> Lot Number:.....</div><div><p>- Wear Gloves while using the instruments</p><p>- Be careful of the sharp point of the instruments, if any</p><p>- Be careful of the moving parts of the instruments.</p><p>- Do not re-use.</p><p>- The instruments must be stored in dry place and must be handled with care to prevent damage</p><p>- Only qualified person should use the healthcare devices.</p><p>- Use only for its intended purpose to ensure maximum effectiveness.</p><p>- After use the instruments should be disposed off according to local laws.</p></div></div></div></div>
IV/6	Environment	Harmless	

**Tata Surgical (Pvt) Ltd.**

  **Director**