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Product Data

Raw Material / Set Component

Item # TAYT 10-205PHGS

Sterile: ■

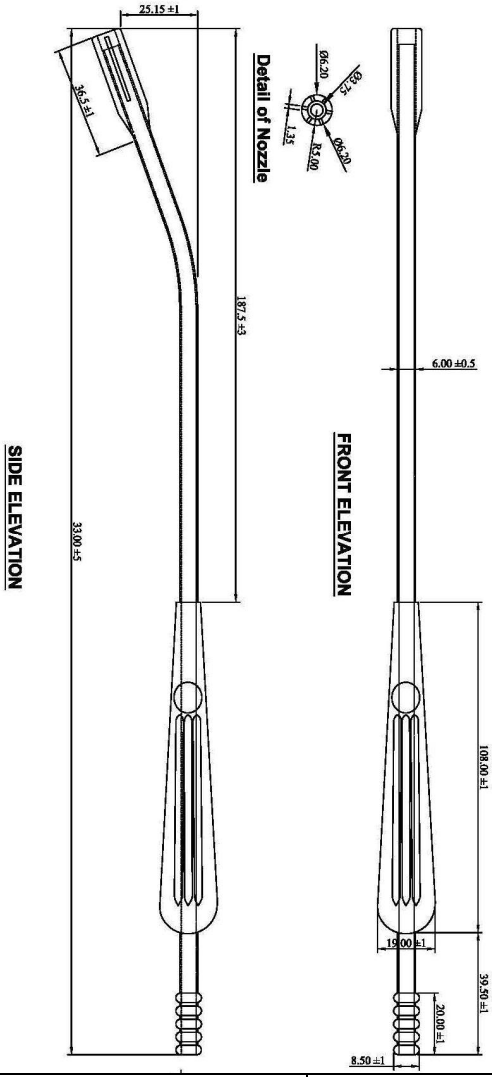
Non sterile □

Revision	Date	Description of change
0	May, 2024	Up to date and completion of product data

I- Product Description & Classification

I/1	Name:	*YANKAUER SUCTION TUBE ROUND SHAPE PLASTIC HANDLE*
I/2	General description:	*YANKAUER SUCTION TUBE ROUND SHAPE PLASTIC HANDLE 33CM, Stainless Steel,*
I/3	Classification - Rule:	Class IIa (Sterile), according to Rule 6 Annex IX of Directive 93/42/EEC
		Justification: Surgically Invasive, transient use, Single use

I/4 Drawing:



I/5	Design:	Dimensions of device :	Please see above
		Sterile packaging:	Sterile Packaging (Medical Paper)
		Shipping packaging: Carton	Carton Dimensions: 11”x7.50”x7”

II- Description of use and operating of device

II/1	Application/ Intended Use:	*General surgery suction tubes are used for removing fluid and debris from confined surgical sites during medical and surgical procedures.*

III- Composition

III/1	Raw materials:	Handle	PLASTIC
		YANKAUER tube	Stainless steel AISI 304
		Ref. Standards	ASTM F899-11 & ISO 7153-1

III/2

INSPECTION AND TESTING

Machine parts :

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.

Assemble devices :

After completion of assembling processes each assemble 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.

Polished devices :

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

Finished devices :

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.\

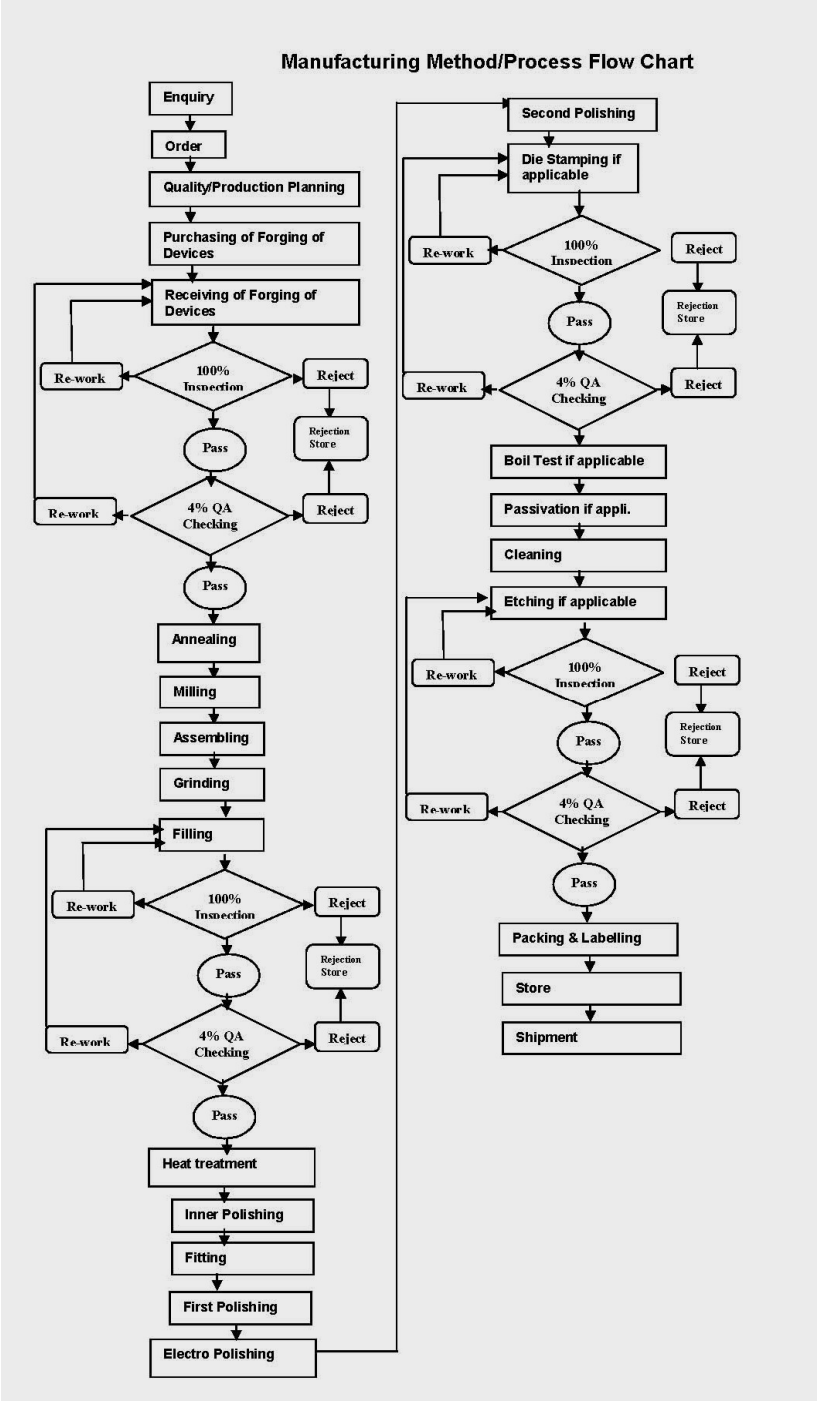
Lab Tests :

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.

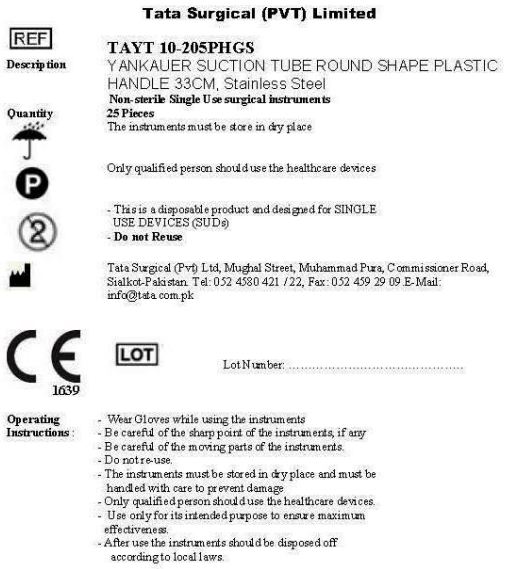
III/3	Average weight of device:	Approxmate: 98 grams

IV- Methods of manufacturing

IV/1



IV/2	Sterile Packaging:	Box: Pieces/Box:	10 Pieces Sterile Packaging according to ISO 11607-1:2019 & ISO 11607-2:2019
IV/3	Cleanroom	ISO 14644-1:2015 (Class 8) Cleanroom microbial and physical testing performed annually Cleanroom operating parameters: Temperature 16~28°C, Humidity 30~70%, Pascal Pressure 15~25Pascal	
IV/4	Shipment packaging:	Carton: Boxes/Carton	10 Boxes
IV/5	Labelling: According to Directive 93/42 CEE Annex I § 13.3 • Name and address of manufacturer: • Name /description of product: • Article no : • Quantity : • LOT no: • Indication for single use: • CE: symbol • Another symbol as defined in EN 15223-1	Example of a label for product to be attached to primary packaging	
IV/6	ETO Sterilization:	Ethylene Oxide Sterilization Services (EOSS), ISO 13458:2016 certified by SGS Ethylene Oxide Sterilizer volume 3 cubic metre, process established according to ISO 11135:2014. Process parameters: Temperature 48~54°C, humidity 60~80%RH, pressure 60Kpa, Mass 30% Ethylene Oxide & 70% Carbon Oxide, Gas concentration in mg/L 600, Weight of gas in KG total gas weight is 30kg. ETO: 6 kg& CO: 24kg.	
IV/7	Environment	Harmless	



Tata Surgical (Pvt) Ltd.
TATA
Director