

Date: 12/04/23

To,  
The Concerned Authority,  
PLI Scheme for Medical Devices Manufacturing,  
Department of Pharmaceuticals,  
New Delhi, INDIA.

Sub: PLI for Medical Devices – Round IV Application – MAJiK Medical Solutions

Dear Sir/Madam.

With regards to product category, we have applied for and description of product, at time of Round III we have described the product as Reinforced Thermo Plastic Medical Tubing used for Medical device applications such as Catheters, Sheaths. For Round IV application we have detailed the product as “Catheter Tubing”. Even though the description is different, the product that we make is still the same as before. MAJiK Medical, manufactures Catheter tubing for Cardiovascular and Neurovascular applications among many other vascular applications.

S. No.	Name of Applied Products under Other Products in TS	Technical Specification	Brief Description	Intended Use	Instruction of Use	Sample Photograph
1	Catheter Tubing (Cardiovascular)	4 Fr to 12 Fr in Diameter (1.3 mm to 4 mm) 30 cm to 150 cm in length	Catheter Tubing at this size is used for Cardio Vascular Applications, to treat blockages in heart vessels.	Guide Catheter for Cardiac Stenting, Heart Valve Delivery – to access Coronary Arteries. <b>(Appendix A)</b>	Used for treatment of Cardio, peripheral Vascular applications. PTCA applications, PAD Diseases (Appendix A)	See attached
2	Micro - Catheter Tubing (Neurovascular)	1.7 Fr to 4 Fr in Diameter (0.7 mm to 1.3 mm) 150 cm in Length	Catheter Tubing at this size is used for Neuro Vascular Applications, to treat Brain Aneurysms	Neuro Vascular Coil Delivery – To access Neuro arteries. <b>(Appendix A)</b>	Used for treatment of Neuro vascular Aneurysms and Flow Divertors. (Appendix A)	See Attached.

Via this letter we would like to detail you more about the products we manufacture and provide additional details to the committee, on our products and manufacturing capabilities, what we bring to “Make in India” Via these products and why as a company MAJiK Medial is a “best fit” for any Medical Devices linked PLI schemes.

We have re-applied for the scheme presenting a new application but would like to detail our product more and how MAJiK Medical is reducing the import dependency for India and increasing the export potential through our products. As mentioned in the previous application, this is a very unique product that NO OTHER COMPANY in India are manufacturing and is Hugely IMPORT dependent. MAJiK Medical has reduced that import dependency for all Medical Device firms and MAJiK also exports these products to other countries. We are the only company doing these products in India and we were sure of our application, in that sense.

We kindly request you to go through some of the detail in below pages, with regards to our candidacy for the new PLI scheme.

If given a chance, we can also present in-person and provide more details about the product and manufacturing capabilities. Thank you.



Rajesh Kalavalapally,  
Founder/CEO  
MAJiK Medical Solutions Pvt. Ltd.

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**Additional Details:**

**Company Name:** MAJiK Medical Solutions Pvt. Ltd.

**Category Applied Under:** Category B

**Target Segment # 3** - Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices.

**Indicative Eligible Products** - Needles-Anaesthesia, Syringes-Anaesthesia, Anaesthesia Kits, Masks – Anaesthesia, Biopsy Kits- Renal, Dialyser reprocessing system, Lithotripters-Extracorporeal –Renal and **other products\*** in this target segment.

**Name of the Product:** Catheter Tubing (in Particular specialty Vascular Catheters)

MAJiK manufactures Catheters that are used for Cardio Vascular, Respiratory, Neuro Vascular applications. The generic term used for the tubing component is reinforced thermos plastic tubes. Catheter tubing that MAJiK manufactures comes under “Vascular type of Catheters”, which are used for applications such as Cardio Vascular Procedures, Respiratory diagnostic Catheters and to treat other vascular diseases.

**Appendix A - Catheter type Medical Device Applications – Intended Use:** Guide Catheter, Neuro Vascular Catheter.

Please refer to **Appendix A** of procedural and Intended usage of Catheter by Physicians in Cath Labs.



**APPENDIX A: Intended Clinical Use of Catheter Products**

**Intended Use**

Intended Use of products that MAJiK manufactures is in the vascular system, blood carrying vessels (arteries and veins). All the cardio vascular and Peripheral products that MAJiK manufactures goes into the vascular system.

Delivery Sheath and Catheter tubing, that MAJiK manufactures, are key components in Medical Devices such as Guiding Catheters used for cardiology, Angiographic catheters for Coronary Angiography, stent-graft delivery devices, Coronary stenting procedures, Neuro Vascular Aneurysm treatment, Nitinol Stent delivery systems to treat Peripheral Arterial Diseases (PAD) and Lower leg arterial disease.

Medical Device Name	Class	Application and Duration in body
Coronary Guiding Catheters	B	Cardiology – 1 to 2 hrs
Diagnostic Catheters	B	Cardiology/Neurology/Endoscopy – 30 min to 2 hrs
Stent Graft Delivery Sheath	NA	Peripheral Vascular – 1 to 3 hrs
Nitinol Self Expanding Stent Delivery Sheaths – Peripheral and Tibial Arteries	NA	Biliary/Peripheral vascular/Tibial Vascular – 1 to 3 hrs
Abdominal Aortic Aneurysm Graft Delivery Sheaths	NA	AAA – 1 to 3 hrs

**Clinical Purpose and Site of Use for Reinforced Thermo Plastic Tubings: (Catheter Tubings)**

**Guide Catheters /Angioplasty Catheters:**

**Clinical Purpose:**

- Used to facilitate of stents, lasers etc
- Catheter makes into vessel with such as coronary



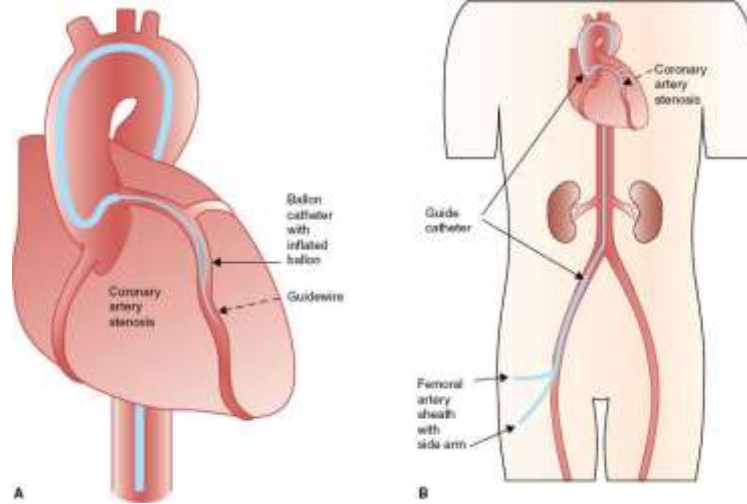
the placement balloons ,  
easier to enter other devices

Catheter Tubing for Coronary Interventions

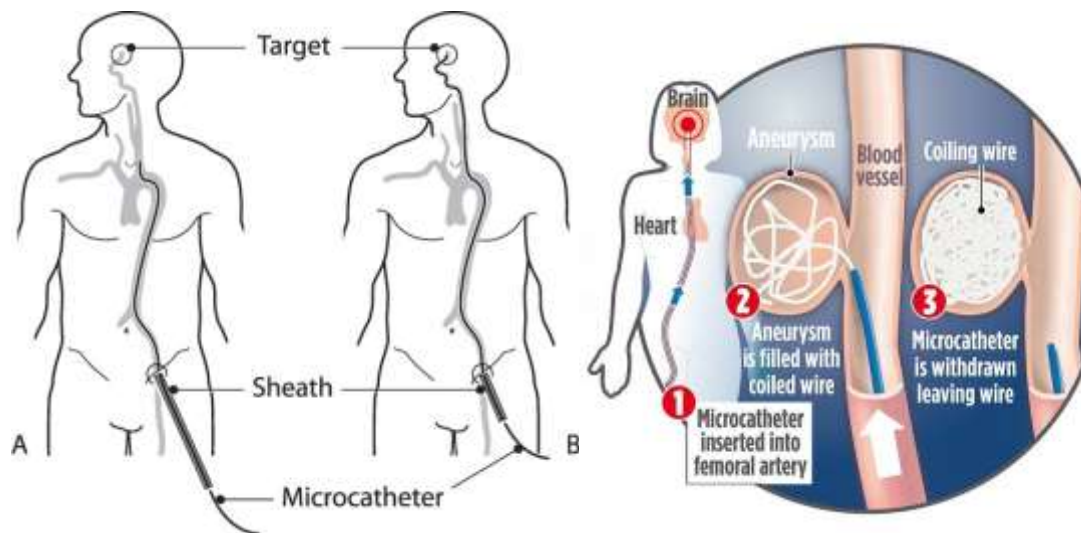
cardiac stents,  
balloons etc during  
stenting  
procedures.

Site of Use:

- Used in heart for placing stent
- Coronary applications
- Peripheral applications



**Microcatheters:**



These catheters are in micro size so that they can be inserted into Neuro vessels for treating blockages and aneurysms.

Microcatheters used in cardiovascular applications generally run under 6 Fr, While neurovascular micro-catheters can run as small as 2 Fr

They are most commonly used in small vessel or selective diagnostic and interventional procedures.

When an application requires an ultra-thin device for delivery, diagnosis, or mapping, a micro catheter will most likely be used.

Clinical Purpose and Site of use:

- To treat aneurysms in the upper neck and head
- To access neuro arteries





## GUIDING CATHETER

ENGINEERED FOR CONTROLLED GUIDING™

- ❖ Large inner lumen facilitates easy insertion of interventional devices
- ❖ Ultra soft tip for safe atraumatic engagement into the ostium
- ❖ Stainless steel Braiding provides more precise torque control and accurate positioning.
- ❖ Material and Construction of distal shaft enhances the backup support for uninterrupted PCI.



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## Microcatheter

Engineered to Navigate and Deliver™

- ❑ Available in 0.017, 0.021, 0.025, 0.027, 0.029, 0.032 Inner Diameters
- ❑ Working Lengths up to 165cm
- ❑ PTFE liner provides smooth surface easy delivery of therapeutic agents and devices.
- ❑ Stainless steel Braiding with variable density provides pushability and distal flexibility.
- ❑ Multi segments along the length for rigidity and flexibility.
- ❑ P10Ir marker band at distal end for better visibility under fluoroscopy.
- ❑ Second marker band at 1cm away from the tip for easy positioning.
- ❑ Hydrophilic coating for smooth outer surface
- ❑ Compatible with DNSO



**Intended Use:** Microcatheter is intended for general intravascular use, including the peripheral coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

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