



CERTIFICATE

# Certificate of Compliance

## CE

We hereby declare that the technical file of product class 1 complied with the requirement of the Medical Council Directives 93/42/eec of June 1995

**Applicant** : **MEDORAH MEDITEK PRIVATE LIMITED**  
Certificate No: CE-9876  
Name : **MEDORAH MEDITEK PRIVATE LIMITED**  
Address : 353, PHASE-4, UDYOG VIHAR, GURGAON, HARYANA, 122015 (INDIA)  
Products Name : Annexure-A

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive 93/42/eec of June 1993 Medical Council directives

**This certificate is issued under the following conditions:**

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislations, the manufacturer shall affix to each device of the references models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample each of above mentioned product. It does not imply an assessment of the whole production.

Date of Certification 17<sup>th</sup> February 2022  
Certificate Expiry (subject to the company maintaining its system to the required standard) 16<sup>th</sup> February 2025

  
Authorised Signatory



Validity of this Certification is successful Annual Surveillance audits to be done.  
This certificate is the property of Brilliant Certification & Inspection Limited and shall be returned immediately on request, Brilliant Certification & Inspection Limited is Accreditation by UKAC ([www.ukaccredited.co.uk](http://www.ukaccredited.co.uk))  
9 Mercury Park, HP10 0HH Saint Mary Church London. UK  
Validity of this certificate can be verified at [www.bciert.co.uk](http://www.bciert.co.uk)



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**Name**

: **MEDORAH MEDITEK PRIVATE LIMITED**

**Address**

: 353, PHASE-4, UDYOG VIHAR, GURGAON, HARYANA, 122015  
(India)

**Annexure**

: A

**Product Name**

: Ercp Guidewire, Stent Introducer Set/ Stent Pusher, Needle Knife, Percutaneous Endoscopic Gastrostomy ( Peg ) Kit, Stone Extraction Balloon, Sphincterotome, Band Ligator/ Endoscopic Ligation Kit, Biopsy Forceps, Foreign Body Removal Net, Biliary Balloon Dilator, Balloon Dilator For Esophagus/ Pylorus/ Duodenum/ Colon, Y-Connector, Angiographic Needle, Manifolds, Sclerotherapy Needle, Biliary Stone Retrieval Basket, Ptca Kit, Eus/Ebus Needle, Biliary/Pancreatic Plastic Stents, Biliary Metal Stents, Esophageal Metal Stent, Colonic Metal Stent, Duodenal Metal Stent, Tracheal Metal Stent, Pseudocyst Stent, Hemoclips, Polypectomy Snare & Inflation Device

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