



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/244-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER:

Aster Medispro Private Limited

S.P.181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate, Jigani Industrial Area, Jigani, Bangalore – 560 105, Karnataka (INDIA)

DEVICE/S:

Urology Catheters

MODEL/S:

- ✓ Ureteral Catheter with variants:
Close Tip (CT), Open Tip (OT), Angle Tip (AT), Cone Tip (CT), Whistle Tip (WT)
- ✓ Malecot Catheter
- ✓ PCN Catheter
- ✓ PCN Catheter With Needle
- ✓ Suprapubic Catheter
- ✓ CIC Catheter
- ✓ Tiemann Catheter
- ✓ Re-Entry Malecot Catheter
- ✓ PCN Catheter Set
- ✓ Malecot Catheter Set
- ✓ Urodynamic Catheter
- ✓ Amplatz Sheath
- ✓ Ureteral Access Sheath

FIRST ISSUE: 03/12/2020

CURRENT ISSUE: 03/12/2020

REVISION Nr.: 00

EXPIRING DATE: 27/05/2024

Dipl.-Ing. Feridoon Sergizzeera
MTIC INTERCERT Certification Body