



# C E R T I F I C A T E

## FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/283-2021

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 Stents**

**MODEL/S:**

*see list of all models in annex 1*

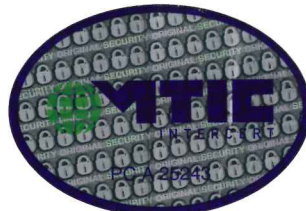
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*This certificate is also made of n. 1 annex of n. 1 page.*



*[Signature]*  
Dipl.- Ing. Feridoon Sergizzarea  
MTIC INTERCERT Certification Body



# C E R T I F I C A T E

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/283-2021

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

- ✓ Ureteral / Double J Stent with Clamp (C), With Guide wire (G), With Clamp + Guide wire (CG), With Suture (S), With Suture + Guide wire (SG), With Suture + Clamp (SC), With Suture + Clamp + Guide Wire (SCG) with variants DJSBES (Both Ends Single Loop), DJSOEM (One End Multi Loop), DJSBEM (Both Ends Multi Loop) OEO (One End Open), BEO (Both Ends Open), BEC (Both Ends Closed)
- ✓ Loop Stent with variants One End Open (OEO), Both Ends Open (BEO)
- ✓ Prostate Stent
- ✓ Urethral Stent
- ✓ Endopyelotomy Stent with variants One End Open (OEO), Both Ends Open (BEO)
- ✓ Tumor Stent with variants Both Ends Open (BEO)
- ✓ Mono J Stent with variants One End Open (OEO), Both Ends Open (BEO)
- ✓ Guidewire with variants J Tip (J), Straight Tip (S)
- ✓ Long Pusher for Double J Stent

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