F-PC-DM-14-01-01 Rev.0.1 en



## CERTIFICATE

## **FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE**

n. 0068/QCO-DM/245-2020

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 Dilators

MODEL/S: ✓ Ureteral Balloon Dilation Catheter ✓ Ureteral Dilator ✓ Fascial Dilator

✓ Nottingham Dilator
✓ Meatal Dilator
✓ Amplatz Renal Dilator Set

✓ Urethral Filliform Dilator ✓ Fascial Dilator Set ✓ Urethral Dilator

✓ Ureteral Dilator set
✓ Renal Dilator

FIRST ISSUE: 03/12/2020 CURRENT ISSUE: 03/12/2020 REVISION Nr.: 00 EXPIRING DATE: 27/05/2024

Dipl.- Ing. Feridoon Sergizzarea NTIC/INTERCERT Certification Body

MTIC INTERCERT s.r.t. - Via Moscova, 11 - 20017 RHO (MI) - ITALY www.mticert.org