Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-5964

Manufacturer

Name : **MEDTECH DEVICES**

Address : **F-45, 2nd Floor, Okhla Industrial Area, Phase-1, New Delhi-110020, India**

Product : **Medical Devices**

Description : **HEMODIALYSIS CATHETER KIT & ACCESSORIES - LONG TERM & SHORT TERM, CVC KITS & ACCESSORIES, MANIFOLD & ACCESSORIES, GUIDEWIRES, PTCA KIT & ACCESSORIES, ANGIO KIT & ACCESSORIES, INTRODUCER SHEATH KIT & ACCESSORIES, BLOOD LINE SET, A.V. FISTULA NEEDLE, INTRODUCER NEEDLE, C.T. CONNECTION TUBE ,PLAIN & SPIRAL , EXTENSION LINE, HIGH PRESSURE TUBING, PRESSURE MONITORING LINE, HIGH PRESSURE SYRINGES, SPIKE, J TUBE FOR C.T. & ANGIO, BIOPSY GUN & BIOPSY NEEDLE, PROCEDURE KIT / DRESSING KIT, CONTROL SYRINGES, TRANSDUCER PROTECTOR, INFLATION DEVICE, BONE MARROW BIOPSY SYSTEM, I.V. CANNULA, THREE WAY STOPCOCK, FOLLEY CATHETER, ORTHOPAEDIC SUCTION SET, ABSORBENT HEMOSTATIC PRESSURE DRESSING, DIALYZER REPROCESSER MACHINE & ENDOTOXIN TEST MACHINE, HAND CONTROL PENCIL, HEMOPERFUSION MACHINE, HEMODIALYSIS MACHINE, PACING LEAD, CRRT MACHINE**

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Medical Devices 93/42/EEC as Amended 2007/47/EC.

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.

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 of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	16th August 2024
1st Surveillance Audit Due	15th August 2025
2nd Surveillance Audit Due	15th August 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	15th August 2027

Authorised Signatory

UK Certification & Inspection Ltd.