

Certificate of Compliance



We hereby declare that the technical files of manufacturing unit as detailed below, complies with the requirements of MDD 93/42/EEC as amended by 2007/47/EC concerning medical device

MANUFACTURER

COMPANY NAME : - HI-TECH MEDICARE DEVICES PVT. LTD.

ADDRESS-1 : - H-16/1, UPSIDC, INDUSTRIAL AREA NAINI, PRAYAGRAJ-211010, UTTAR PRADESH, INDIA

PRODUCTS : - DESIGN DEVELOPMENT, MANUFACTURING, SUPPLY OF IV CANNULA AND PROCUREMENT AND SUPPLY OF STERILE/NON-STERILE DISPOSABLE MEDICAL DEVICES FOR INFUSION THERAPY, PERFUSION THERAPY AND GENERAL SURGERY

The Certification body has performed an audit of above product quality system covering the design, manufacturing and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to MDD 93/42/EEC as amended by 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 with applicable CE Requirement or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation and CE Requirement, the manufacturer shall affix to each device, of the referenced models.
5. The CE Certificate 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 with EN standard requirement. 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

Certificate Number: UQ-3772

Validity of this certificate can be verified at www.ukglobal.uk/Verify

Initial registration date : 12/10/2024

Issue date : 12/10/2024

1st surveillance on or before : 11/09/2025

2nd surveillance on or before : 11/10/2026

Valid until : 11/10/2027

Authorised Signatory



This certificate is the property of UKGlobal Certification & Inspection Limited and shall be returned immediately on request.

71-75 Shelton Street Covent Garden London United Kingdom WC2H9JQ

Website : www.ukglobal.uk, enquiries@ukglobal.uk

Company No.118478