



Certification & Inspection

Certificate of Compliance



We hereby declare that the technical file of product complied with the requirements of Medical Device Regulation - (Council Regulation 2017/745).

Certificate No.: CE-5400

Manufacturer

Name : MEDISTER INFECTION CONTROL SYSTEMS PRIVATE LIMITED

**Address : REG. ADDRESS: - G-119, GROUND FLOOR, SHAGUN ARCADE PREMISES LTD., NEAR DINDOSHI BUS DEPOT, GEN A.K. VAIDYA MARG, MALAD (EAST), MUMBAI-400097, MAHARASHTRA, INDIA
FACTORY ADDRESS: UNIT R6-R6A, QURESHI IND AREA, SAGAR INDUSTRIAL ESTATE, ZILU PARAB ROAD, CHINCHOTI, OFF KAMAN BHIWANDI NAKA, NAIGAON (E), PIN: 401208 TAL : VASAI, DIST :-PALGHAR, MAHARASHTRA, INDIA**

Products : STEAM STERILIZERS - VERTICAL AUTOCLAVES, HORIZONTAL AUTOCLAVES, CLASS B AUTOCLAVES, ETO STERILIZERS

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Council Directive on Medical Device Regulation - (Council Regulation 2017/745).

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
4. 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	26 th February 2024
1 st Surveillance Audit Due	25 th February 2025
2 nd Surveillance Audit Due	25 th February 2026
Certificate Expiry (subject to the company maintaining its system to the required standard)	25 th February 2027

Daniel..

Authorised Signatory

