



# Certificate of Compliance

Hereby Declare That the Technical File of Product Complied with the Requirement of Medical Devices Directive 93/42/EEC & LVD Directive 2014/35/EU.

## HYBRID BIOMEDICAL EQUIPMENTS & ALLIED TECHNOLOGIES

**Office Address: 517, Manish Chamber, Sonawala Lane, Goregaon-East, Mumbai 400063, Maharashtra, India.**

**Factory Address: Gala No.9, Ground Floor, Building No.4, Hriday Industrial Hub, Chinchoti, Vasai-East, District-Palghar- 401208, Maharashtra, India.**

### MANUFACTURER

**PRODUCT: - Dry Heat Sterilizer, Drying Cabinet, Fluid Warmer, Blanket Warmer, Ovens, Incubators, (Contrast Media Warmer) Thermal Disinfectant, Bed Pan Washer, Macerators, Endoscope Cabinet, Scrub Sink, S.S Doors for OT, Hospital Beds, CSSD Furniture, Autoclave, Steam Steriliser, Plasma Steriliser & H2O2 Vapour Steriliser & Grossing Station.**

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 Medical Devices Directive 93/42/EEC & LVD Directive 2014/35/EU

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.

**Certificate No.: 2280055126CE**

**Initial Registration Date: 17/12/2022**

**Issuance Date: 17/12/2022**

**Date of Expiry: 16/12/2025**

**1<sup>ST</sup> Surveillance Audit Due: 16/12/2023**

**2<sup>ND</sup> Surveillance Audit Due: 16/12/2024**



  
Auth. Signatory

**DGACERT MANAGEMENT SYSTEM PVT. LTD.**

Email: [info@dgacert.com](mailto:info@dgacert.com) | Web: [www.dgacert.com](http://www.dgacert.com)

**The Validity of this certificate can be verified at [www.dgacert.com](http://www.dgacert.com)**

This certificate of registration remains the property of Dgacert Management System Pvt. Ltd. and shall be returned immediately upon request.

DGACERT is accredited by UK Akkreditering Certification Forum Limited, UK ([www.ukacf.co.uk](http://www.ukacf.co.uk))  
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