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Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directive Medical Device Regulation - (Council Regulation 2017/745) and (98/79/EC) In-Vitro Diagnostic Devices Directive.

Manufacturer:

NAME : SHREYA MEDICAL SYSTEM

ADDRESS: GROUND FLOOR, PLOT NO. 326, GREEN PARK, SR. NO. 96/1/1, NEAR HP PETROL PUMP, LOHEGAON, PUNE- 411047, MAHARASHTRA, INDIA.

PRODUCTS : "DESIGN, SUPPLY. INSTALLATION, MANUFACTURER, SALES & SERVICES OF MODULAR OPERATION THEATER, MODULAR IVE LAB & OT, SCRUB STATION, MEDICAL GAS PIPELINE AND TOTAL HOSPITAL FURNITURE, SKILL LAB, CCL, MICU,PICU, PACU, BURN UNIT, CSSD, HOSPITAL INTERIOR, & HOSPITAL AIR CONDITIONING."

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to 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 not changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation requirements in the medical directive, the manufacturer shall affix the CE marking to each device of the above referenced models.
5. 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

Statements:

This Certificate declares that the products type I model described above complies with the mentioned above European Standard(s)

Remarks:

This certificate of complies is based on the evaluation of a sample of the above mentioned products. It does not imply and assessment of the mass-production of the product. This certificate holder may use this certificate in connection with the test report. The certification body should be informed (revision of technical file) for any modification or alterations made to the aforementioned product type(s), including design and manufacture and for extension to the existing scope of application

Certification No: **UK-ARCT-25-14210729**

Date of Initial Registration:	**20/AUG/2025**
1st Surveillance Audit Due:	**19/AUG/2026**
2nd Surveillance Audit Due:	**19/AUG/2027**
Re-certification Due:	**19/AUG/2028**

Authorized Signatory
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