



Certificate of Compliance



We hereby declare that an examination of the quality assurance system has been carried out with the requirements of the national legislation, to which the manufacturer is subjected, pertaining to class I according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC. We UKCert certify that the full quality assurance system confirms with the relevant provisions of the aforementioned directive.

Certificate No.: CE-3815

Manufacturer

Name : **SUPREME ENTERPRISES**

Address : **Plot No. D-39, Sector-B3 UPSIDC Industrial Area,
Tronica City Loni – 201 102, Ghaziabad, Uttar Pradesh India**

Products : **As per appendix of page 1**

Applicable : **IEC 60601-1, IEC 60601-2-46, IEC 60601-1-2, IEC 60601/2/41/IEC**

Standards : **60529/IEC 60601-1-38, IEC 60601-2-52, EN ISO-14155-2:2003,
ISO EN-13485:2012**

Complies with the requirements applicable to it

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 manufacturer's technical documentation, as required for **Class I** device, has been reviewed and found to comply with the requirements.

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 initial registration	27 th December 2022
Date of this Certificate	27 th December 2022
Certificate Expiry	26 th December 2025
Recertification Due (subject to the company maintaining its system to the required standard)	26 th December 2025



Authorised Signatory



page 1 of 2



Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- CE-3815

Manufacturer :

SUPREME ENTERPRISES

Address:

Plot No. D-39, Sector-B3 UPSIDC Industrial
Area, Tronica City Loni – 201 102, Ghaziabad,
Uttar Pradesh India



This certificate referred to above covers the following products like:

Product Name & Models :

Manufacture and Supply of Suction Machines & Their Accessories Models

1. Vacumaxx
2. Instavac
3. Accelerator
4. Minic
5. Powervac
6. Nano AC/DC
7. Smart Lipovac
8. Eterno AC/DC/Pedal
9. Supreme Airforce
10. Hospivac
11. Carevac
12. Primevac
13. Vacuum Extractor
14. Supreme Foot Suction
15. Supreme Plus
16. SURGIVAC



Authorised Signatory



page 2 of 2