



# CERTIFICATE

We hereby declare that the technical file of product complied with the requirement of directives 93/42/EEC Medical Device Directive and IEC 60601 Standard requirements.

**Certificate No.: UO-1040620067K**

**Manufacturer**

Name : Advance Mediplus Pvt. Ltd.

Address : B-71/1B, 2nd Floor, Lawrence Road Industrial Area, Delhi-110035, India

Product : Radiant Heat Warmer, Phototherapy Systems, Bubble C-pap, Oxygen Concentrator, Infant incubator / Transport Incubator, Neonatal Resuscitation Unit, Flow Controlled Nasal C-Pap, Weighing Scale, Syringe Pump, Infusion Pump, Fetal Monitor, Electronic / Electric Operated Hospital Furniture/O.T. Light, Cold Light Source, Fiber Optic Cable, Vein Locator/Viewer, Centrifuge & Bilirubin Meter / Jaundice Meter

Applicable standards: IEC 60601

**MEDICAL ELECTRICAL EQUIPMENT PART-1: GENERAL REQUIREMENT OF SAFETY FOR ELECTROMAGNETIC COMPATIBILITY;**

**PART-2: GENERAL REQUIREMENT OF ELECTRICAL SAFETY.**

The manufacturer's technical documentation as required has been reviewed and found to comply with the requirements. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

**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 EN 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 EN Requirement, the manufacturer shall affix to each device, of the referenced models.
5. The IEC / EN 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

Date of initial registration: 23<sup>rd</sup> May 2020

Date of this Certificate: 23<sup>rd</sup> May 2020

Certificate Expiry: 22<sup>nd</sup> May 2021

Recertification Due: 22<sup>nd</sup> May 2023

Head of Certification



The certificate remains the property of DBS Certifications Private Limited, to whom it must be returned upon request.

**DBS CERTIFICATIONS PVT. LTD.**

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