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CERTIFICATE

Certificate of Compliance

Technical file of the company mentioned below has been inspected and audit has been completed successfully. MDD 93/42/EEC+2007/47/EC Directive of Medical Devices AnnexIIB And ISO 13484:2003 has been taken as references for these processes.

Company Name:
Mediwaves INC

Company Adress
Head office:- B-68, G.T Karnal Road Industrial Area, Delhi- 110033, India
Works: Plot no- 92 HSIIDC, Sector- 57, Phase- IV Kundali, Sonipat (Haryana)

Related Directives and Annex
93/42 EC as amended by 2007/47EC (Medical Devices) class IIB, Rule 9

Product
INFANT RADIANT WARMER, PHOTOTHARAPY UNIT, BABY INCUBATOR, SURGICAL CAUTERY, FETAL DOPPLER, ELECTRIC ICU BED, SYRINGE PUMP AND INFUSION PUMP

Verification to:
IEC-60601-1:2006/AC:2010
IEC-60601-1-2:2007/AC:2010, IEC-60601-1-1-6:2007:2010
IEC-60601-1-8:2007/AC:2010, IEC-60601-2-21:2009
IEC-60601-2-50/AC:2009, IEC-60601-1:2005 & IEC-60601-1:2005

The Regal Register (UK) Ltd. has reviewed manufacturer's technical documentation & Test reports and found it in compliance with above mentioned Directive (s).

This certificate is issued under the following conditions:

1. It applies only to the above referenced set of products. The manufacturer is obligated to assure that all products of the respective model confirm to the type assessed for this certificate.
2. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed subjected to maximum Validity of 3 years.
3. The Certificate validity is conditioned by the positive results of the surveillance audits.
4. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example.

Certificate No. CE- 29591
Originally Issue Date : 01st February 2019
Current Issue Date : 01st February 2019
Certificate Expiry Date : 31st December 2023
Recertification Due Date : 31st December 2023

CE

Authorized Signatory
Regal Register (UK) Ltd.

Statement:
This certificate of conformity based on the evaluation of a sample of the above mentioned products. It does not imply an assessment of the serial production of the product. The certification body should be informed [illegible] for any modification or alterations made to the aforementioned product type(s). The manufacturer is responsible for the product and ensuring that all manufactured products are in compliance with the specifications detailed in the technical

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ANNEX I

Product

Infant Radiant Warmer with cradle: P-001 (a)
Infant Warmer Economical Series: P-001 (b)
Warmer With bassinet: P-001(c)
Warmer Without cradle: P-001 (d)
Open Care System: P-001(e)

Electric ICU Bed : EHB-01 and EHB-02

Phototherapy unit, LED & CFL: P-003

Syringe Pump : HK-400

Baby Incubator, Transport incubator.

Electro surgical unit/ Surgical cautery/Diathermy: 100Watts, 250Watts & 400Watts

Infusion Pump : HK-100I

Fetal Doppler: Hand Model & Table Model with Digital heart beat display.

Verification to: **Standard**
IEC-60601-1:2006/AC: 2010
IEC-60601-1-2:2007/AC: 2010, IEC-60601-1-6:2007:2010
IEC-60601-1-8:2007/AC: 2010, IEC-60601-2-21:2009
IEC-60601-2-50/AC: 2009, IEC-60601-1:2005 & IEC-60601-1:2005

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Statement: