## eurotech

## Certificate of Conformity

We confirm that the technical documentation for the below mentioned product (Medical Devices of the Class I) according to the Council Directive 93/42/EEC as amended (2007/47/EC)

Motorized ICU Bed (5101, 5102, 5103) & **Birthing Bed Motorized (5301)** 

Manufactured by company

## MEDITEK ENGINEERS

W-13 (A) ADDITIONAL MIDC, NEAR HOTEL KRISHNA PALACE, AMBERNATH (E) - 421 506, THANE, MAHARASHTRA. INDIA.

complies with the applicable requirements of the Directive 93/42/EEC as amended (2007/47/EC) and appropriate Harmonized European Standards IEC 60601-1:2005+AMD:2013 & IEC 60601-2-52: 2015.

Referring to the intended use, the Certification Body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to above mentioned Directive and appropriate Harmonized European Standards. The compliance with the EN Standards has been ascertained and documented in the Test Report No. ITC/TEST/NN/1609/03

This Certificate is issued under the following conditions:

- The Manufacturer's Technical Documentation, as required for Class I Devices, has been reviewed and 1. found to comply with the requirements in Annex VII, Section 3.
- 2. It applies only to the above mentioned Medical Devices.
- 3. The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this Certificate.
- Any significant changes in the design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require special audit by Eurotech Assessment and Certification Services Pvt. Ltd. The product liability rests with the Manufacturer or his Representative in accordance with Council Directive.
- After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical 5. Device, CE Marking according to the following example:

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Certificate No. ET/MDD/2017/1093

**Issued On** : March 27, 2017

Valid Up To : March 26, 2022

**Authorized Signature** 

**Eurotech Assessment and Certification Services Ltd.** 

The Certificate remains the property of Eurotech Assessment and Certification Services Ltd. to whom it must be returned on request. Deliberate misuse of certificate will results in cancellation without notification. To check current validity of certificate, log on to URL: www.eurotechworld.net; E-mail: info@eurotechworld.net