eurotech

Certificate of Conformity

We confirm that the technical documentation for the below mentioned products (All Devices except Devices for Self Testing and Annex II Devices) according to the Council Directive 98/79/EC

Automated ESR Analyzer - XC -A -30, KB 202 EM/ ARTOS ELITA, Chemiscan Eliza Micro Plate Reader, Chemiscan Micro Plate Washer, Capillary Bilirubin Analyzer, Fix & Variable Volume Pipette, Ovens & Autoclaves

(For Laboratory Use Only)

Manufactured by Company

KRISH BIOMEDICALS

T - 7& S - 35, PANKAJ CENTRAL MARKET, I.P. EXTENSION, PATPAR GANJ, NEW DELHI – 110 092, INDIA

complies with the applicable requirements of the Directive 98/79/EC (Annex II, Section 4 & 5).

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.

This Certificate is issued under the following conditions:

- 1. The Manufacturer's Technical Documentation, as required for 'All Devices except Devices for Self Testing and Annex II Devices', has been reviewed and found to comply with the requirements in Annex II, Section 4 & 5.
- 2. It applies only to the above mentioned In-vitro Devices/ Equipments.
- 3. The Manufacturer is obligated to assure conformity of all the In-vitro Devices/ Equipments of the respective model to the type assessed by the mean of this Certificate.
- 4. 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.
- 5. After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the following example:

CE

Authorized Signature

Certificate No. : El Issued On : Ja

ET/IVD/2014/882 January 21, 2014

Valid Up to : January 20, 2019

Eurotech Assessment and Certification Services Pvt. Ltd.

The Certificate remains the property of Eurotech Assessment and Certification Services Pvt. 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