

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)

## Re-usable Surgical Instruments

(Cardio Thoracic Surgical Instruments, ENT Surgical Instruments, General Surgery, Gynaecological and Obstetrical Surgery Instruments, Keyhole Surgery Instruments, Tungsten Carbide Surgical Instruments, Urological Surgical Instruments, Neuro Surgery Instruments, Titanium Instruments, Ophthalmic Instruments, Orthopaedic Instruments & Dental Instruments) & Hollowware

Manufactured by Company

## SISCO LATEX PVT. LTD.

MODULE 29, SECOND FLOOR, BLOCK II, SIDCO ELECTRONICS COMPLEX,  
THIRU VI KA INDUSTRIAL ESTATE, GUINDY, CHENNAI - 600 032, INDIA

complies with the applicable requirements of the Directive 93/42/EEC as amended (2007/47/EC).

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 Class I Devices, has been reviewed and found to comply with the requirements in Annex VII, Section 3.
2. It applies only to the above mentioned Medical Devices (Non-sterile).
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.
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 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

Certificate No. : ET/MDD/2023/1420  
Issued On : February 10, 2018  
Re-issued On : March 10, 2023  
Valid Up To : March 09, 2024



*Handwritten signature*

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 result in cancellation without notification. To check current validity of certificate, log on to URL: [www.eurotechworld.net](http://www.eurotechworld.net); E-mail: [info@eurotechworld.net](mailto:info@eurotechworld.net)