Notified Body No. 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0186 QS/NB/b

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIa & Isterile,

Medical Devices for Cardiac Surgery, Airways Management & Transfusion
(For detailed specification refer to Annex)

manufactured by company

SIDD Life Sciences Pvt. Ltd.
Plot No. 4, NH7, MMDA Industrial Estate, Maraimalai Nagar-603209, Tamil Nadu, India

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601074/2011 and 343603415/2016 which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **6th March 2018** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Issued in Zlín, on 12th February 2016
(This certificate replaces the withdrawn Certificate No. 11 0186 QS/NB/a issued on 18th April 2011)

Annex to EC Certificate
No. 11 0186 QS/NB/b

Issued for the company:

SIDD Life Sciences Pvt. Ltd.

Plot No. 4, NH7, MMDA Industrial Estate, Maraimalai Nagar-603209,
Tamil Nadu, India

List of the medical devices covered by the EC certificate:

Membrane Oxygenator

Myocardial Protection System

Cardioplegia Delivery System

Arterial Blood Filter

Adult Bubble Trap

Infant Bubble Trap

Custom/Perfusion Pack

Autotransfusor

Blood Transfusion Filter

Adult Bubble Oxygenator

Cardiotomy Reservoir

Closed Suction System

Chest/Thoracic Drainage System
& its accessories (Bed Side Vacuum Controller)

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