

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60097847 0001

Report No.: 15064188 001

Manufacturer: MEDTRUM TECHNOLOGIES Inc.
7F, Building 8
No. 200 Niudun Road
201203 Shanghai
China

Products:

- Continuous Glucose Monitoring Systems
- Insulin Management Systems

Expiry Date: 2019-02-18

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2014-11-20

Date: 2014-11-20



Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.