EC Certificate

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

Registration No.: HD 60135711 0001

Report No.: 15064188 010

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

Products:
- Continuous Glucose Monitoring Systems
- Insulin Management Systems

Replaces Approval, Registration No.: HD 60097847 0001

Expiry Date: 2023-08-22

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: 2019-02-19

Date: 2019-02-19

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle

S. Liu

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.

Digitally signed by Şarco Alexandru
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