

EC Certificate Directive 93/42/EEC Annex V **Production Quality Assurance** Medical Devices

Registration No.: DD 60147730 0001

Report No.:

15087831 014

Manufacturer:

Zhejiang POCTech Co., Ltd.

No. 1633 Hongfeng Road, Building 11

Huzhou City 313000 Zheijang

P.R. China

Products:

- Continuous Glucose Monitoring Systems

- Sensor of Continuous Glucose Monitoring Systems

Replaces Approval, Registration No.: DD 60115718 0001

Expiry Date:

2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date:

2020-04-08

Date:

2020-04-08

Notified Body

LGA Produ

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.