

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 710130
Issued To: Zhejiang POCTech Co.,Ltd.
No.1633 Hongfeng Road
Building 11
Huzhou City
Zhejiang
313000
China

In respect of:

The design, development and manufacture of mobile Apps that interact with Continuous Glucose Monitoring Systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-03-01**

Date: **2020-03-01**

Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 710130

Issued To:

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NBOG Code	Device name	Intended purpose per IFU
Class IIa		
MD 1111	Software for Continuous Glucose Monitoring Systems	N/A

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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313000
China**

Subcontractor:

Service(s) supplied

Prolinx GmbH
Brehmstraße 56
Düsseldorf
40239
Germany

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 710130
Date: 2020-03-01
Issued To: Zhejiang POCTech Co.,Ltd.
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 China

Date	Reference Number	Action
Current	9756882	New issue

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