

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 continuous glucose monitoring systems and related sterile and non-sterile accessories and mobile software applications.

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: **2021-05-20**

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

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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.

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Supplementary Information to CE 710130

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NBOG Code(s)	Device Description	Intended Purpose
Class IIb		
MD 1302, MD 1111 MDS 7006, MDS 7010	Continuous Glucose Monitoring Systems	Used by adult patients for detecting trends and tracking patterns in adults with diabetes.
MD 1302 MDS 7006	Sensors of Continuous Glucose Monitoring Systems	
MD 1302 MDS 7010	Transmitters of Continuous Glucose Monitoring Systems	
	Receivers of Continuous Glucose Monitoring Systems	
MD 1111	Software for Continuous Glucose Monitoring Systems	

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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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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

CGN Dasheng Electron Accelerator Technology Co., Ltd. **Radiation (E Beam Sterilization)**
NO. 1288 Shexi Rd
Beishe
Lili
Wujiang
Suzhou
Jiangsu Province
215214
People's Republic of China

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**
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Date	Reference Number	Action
01 March 2020	9756882	New issue.
Current	3318201	Added continuous glucose monitoring systems to scope following transfer from another notified body and clarified scope wording to be in line with BSI scope requirements. Updated device table to add new devices following transfer from another notified body. Amended device table to reflect upclassification of the software. Added subcontractor CGN Dasheng Electron Accelerator Co., Ltd., Wujiang City, China for E Beam Sterilization.