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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Supplementary Information to CE 710130

Issued To:

Zhejiang POCTech Co.,Ltd.
No.1633 Hongfeng Road
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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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By Royal Charter

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List of Significant Subcontractors

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

Certificate No:	**CE 710130**
Date:	**2021-05-20**
Issued To:	**Zhejiang POCTech Co.,Ltd.** **No.1633 Hongfeng Road** **Building 11** **Huzhou City** **Zhejiang** **313000** **China**

Subcontractor:	**Service(s) supplied**
CGN Dasheng Electron Accelerator Technology Co., Ltd. NO. 1288 Shexi Rd Beishe Lili Wujiang Suzhou Jiangsu Province 215214 People's Republic of China	**Radiation (E Beam Sterilization)**
Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. No.1 Baisheng Road Development Zone 212300 Danyang Jiangsu People's Republic of China	**Manufacture**
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: **2021-05-20**

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Date	Reference Number	Action
01 March 2020	9756882	New issue.
20 May 2021	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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 October 2021	3540574	Change of legal manufacturer address. Addition of subcontractor Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. for Manufacture.

Inspiring trust for a more resilient world.

20 October 2021

Zhejiang POCTech Co., Ltd.
No.1633 Hongfeng Road
Building 11 & 12
Huzhou City
Zhejiang
313000
China

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 710130	93/42/EEC Annex II excluding Section 4	3540574	Change of legal manufacturer address from: Zhejiang POCTech Co., Ltd., No.1633 Hongfeng Road, Building 11, Huzhou City, Zhejiang, 313000, China to Zhejiang POCTech Co., Ltd., No.1633 Hongfeng Road, Building 11 & 12, Huzhou City, Zhejiang, 313000, China Addition of subcontractor Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. for Manufacture.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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