

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 770429 R000

**Manufacturer:** Zhejiang POCTech Co., Ltd.

**Address:**

No.1633 Hongfeng Road  
Building 11 & 12  
Huzhou City  
Zhejiang  
313000  
China

**Single Registration Number:** CN-MF-000024556

**EU Authorised Representative:** Prolinx GmbH

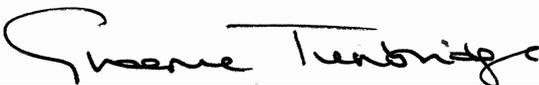
**Address:**

Brehmstraße 56  
Düsseldorf  
40239  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-03-04**

Current Issue Date: **2024-03-04**

Starting Validity Date: **2024-03-04**

Expiry Date: **2029-03-03**

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### Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Continuous Glucose Monitoring Systems	The Continuous Glucose Monitoring System is a real time, continuous glucose monitoring device indicated for the management of diabetes in adult (age $\geq$ 18 years). Interpretation of the System results should be based on the glucose trends and several sequential readings over time. The System also aids in the detection of episodes of hyperglycemia and hypoglycemia. It is intended for single patient use.
Sensors of Continuous Glucose Monitoring Systems	
Transmitters of Continuous Glucose Monitoring Systems	
Application for Continuous Glucose Monitoring Systems	
Follow for Continuous Glucose Monitoring Systems	
View for Continuous Glucose Monitoring Systems	

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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3676294	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.