Declaration of Conformity

Manufacturer (Name and Address)	Zhejiang POCTech Co., Ltd. Add.: No.1633 Hongfeng Road, Building 11 & 12, Huzhou City 313000, Zhejiang, China
Manufacturer SRN	CN-MF-000024556
Authorized Representative (Name and Address)	Prolinx GmbH Add: Brehmstr. 56, 40239, Duesseldorf, Germany
Authorized Representative SRN	DE-AR-000005129
Produced by (Site of manufacture) (Name and Address)	Zhejiang POCTech Co., Ltd. Add.: No.1633 Hongfeng Road, Building 11 & 12, Huzhou City 313000, Zhejiang, China
Notified Body (Name and Identification Number)	BSI Group The Netherlands B.V. 2797
Conformity Assessment Procedure	(EU) 2017/745 Annex IX
EC Certificate(s)	MDR 770429
Expire date of EC Certificate	2029-03-03
Common Specifications (CS)	N/A
Product and trade name	Continuous Glucose Monitoring Systems
EMDN code	Continuous Glucose Monitoring Systems: Z1204011502 Sensor:Z1204011585
Classification	Class IIb

System model	Basic UDI-DI	Intended Use	Components model		Basic UDI-DI
Model: CT3	69711412 0CT3K6	The real time continuous glucose monitoring (rtCGM) system is intended for use in persons age 14 years and older by providing real-time continuous readings, graphs and alerts of interstitial fluid glucose levels. Interpretation of the rtCGM System results should be based on the glucose trends and several	Sensor Model	CT-302	697114120CT30257
			Transmitter Model	CT-300D	697114120CT300D2K
			AnytimeWell	/	697114120CGMWAPPJG
			AnytimeFollow	/	697114120CGMFAPPER
			AnytimeView	/	697114120CGMVPCC7
Model:CT3A			Sensor Model	CT-312	697114120CT3125A
			Transmitter Model	CT-301D	697114120CT301D2N
			AnytimeWell	/	697114120CGMWAPPJG
			AnytimeFollow	/	697114120CGMFAPPER
			AnytimeView	/	697114120CGMVPCC7

Model:CT3C		sequential readings over time. It is intended for single patient use.	Sensor Model	CT-312C	697114120CT312C2U
			Transmitter Model	CT-301DC	697114120CT301DC2K
			AnytimeWell	/	697114120CGMWAPPJG
			AnytimeFollow	/	697114120CGMFAPPER
			AnytimeView	/	697114120CGMVPCC7

We, the undersigned, hereby declare that the medical device(s) described above conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the applicable provisions of Directive 2014/53/EU of the European Parliament and the Council of 16 April 2014 on the market of radio equipment. The declaration is made in accordance with Annex IV of the Medical Device Regulation and is issued under the sole responsibility of the manufacturer.

Place: Huzhou Date of Issue: 2024.03.04

Signature:

Name: Duan Guohong

Position : Person Responsible for Compliance/Management Representative