

POCTech

EC Declaration of Conformity

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:

Name: Zhejiang POCTech Co., Ltd. Address: No.1633 Hongfeng Road, Building 11-12,Huzhou City 313000, Zhejiang, China

European Authorized Representative:

Name: Medwheat Tech Service GmbH Address: Max-Planck-Straße 4 85609 Aschheim b. München Germany

Product name: PC Software for Continuous Glucose Monitoring Systems

Classification: Class |

Rule: According to Rule11,

Conformity assessment procedure: Annex IX

We confirm our product can meet the requirement of Medical Device Regulation (EU) 2017/745 and the following harmonized standards:

EN ISO 13485:2016/EN ISO 14971:2019 /IEC 62304: 2015

This declaration of Conformity is in our sole responsibility.

Signature:

Position:



Date: 707-09-1}