

Number: 6132038CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

SYAI HEALTH TECHNOLOGY PTE. LTD.

112 ROBINSON ROAD #03-01 ROBINSON 112

SINGAPORE

SRN ID.: SG-MF-000041645

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6132037CN

Authorized Representative: **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager

First Issued: 11 April 2024

Date: 16 April 2025

Expiry date: 1 April 2029

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

BLOOD SUGAR MONITORING SYSTEMS (Z12040115, Class IIb)

Group of Devices: Continuous Glucose Monitoring System

Intended Purpose:

Continuous Glucose Monitoring System is intended for adults (18 and above) with diabetes mellitus who need to monitor their glucose levels. The system is indicated for measuring interstitial fluid glucose levels in intended adult users and can provide users with real-time glucose readings, glucose trend and fluctuation characteristics, and alert information such as high/low glucose alerts. It is intended to supplement blood glucose testing, allowing individuals for better management of diabetes, helping individuals make decisions about medication, diet and exercise, and improving quality of life for individuals with diabetes. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Continuous Glucose Monitoring System is intended for single patient use.

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	11 April 2024	6132037CN02	first issue
1	10 October 2024	6132037CN03	revised
2	16 April 2025	6132037CN04	revised

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