

EU Declaration of Conformity

MANUFACTURER (name and address):	Syai Health Technology Pte.Ltd. 112 ROBINSON ROAD #03-01 ROBINSON 112 SINGAPORE
SRN:	SG-MF-000041645
AUTHORIZED REPRESENTATIVE (name and address):	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany

PRODUCTS:

Product Name / Trade name	Product number / catalogue number	Basic UDI-DI	Description / intended purpose	Classification
Continuous Glucose Monitoring System	X1	88850212601VJ	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.	Class IIb, rule 10 & rule 8 & rule 11

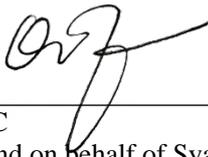
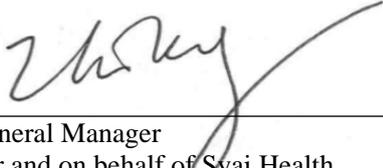
<Continuous Glucose Monitoring System >		
CONFORMITY ASSESSMENT ROUTE:	MDR 2017/745 Annex IX	
Picture of product:		
EMDN	Z12040115	

We herewith declare under our sole responsibility that the above-mentioned products

1. are in conformity with the applicable provisions of Regulation (EU) 2017/745 on medical devices (MDR); and
2. bear the CE marking of conformity under this Regulation.

All supporting documentation, including the technical documentation, is retained at the premises of the manufacturer and will be made available to the competent authorities upon request.

STANDARDS APPLIED:	Applied standards are listed in the General Safety and Performance Requirements Checklist
NOTIFIED BODY:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands Notified body number: 0344
EU CERTIFICATE:	6132038CE01
EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE:	N/A

SIGNATURE:	QIU YUWEI 16.08.2025 	WANG ZHIHUA 16.08.2025 
	PRRC For and on behalf of Syai Health Technology Pte.Ltd.	General Manager For and on behalf of Syai Health Technology Pte.Ltd.