

Document No.: TCF-CGM-4.3 (Ver.: A/2)

EU Declaration of Conformity

MANUFACTURER
(name and address):
Beijing Synapsor Artificial Intelligence Co., Ltd.
Room S408, Floor 4, Building 7, Yard 10, Xibeiwang East
Road, Haidian District, Beijing, China

SRN:
CN-MF-000022964

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/ Syai®	X1	69751306101UG	Syai® 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 Syai® Continuous Glucose Monitoring System is intended for single patient use.	Class IIb, rule 10 & rule 8 & rule 11

CONFORMITY ROUTE:
ASSESSMENT MDR 2017/745 Annex IX
Picture of product:



EMDN: Z12040115

We herewith declare under our sole responsibility that the above-mentioned products meet the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

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

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number

Place, Date of
issue:

SIGNATURE:


WANG ZHIHUA 11.04.2024

General Manager
For and on behalf of Beijing
Synapsor Artificial Intelligence
Co., Ltd.


QIU YUMEI 11.04.2024

Regulatory Affairs Supervisor
For and on behalf of Beijing
Synapsor Artificial Intelligence
Co., Ltd.