DEKRA Certification B.V.

CERTIFICATION NOTICE

Number : 6132037CN	Initial date : 13 September 2023
Version : 02	Version date : 11 April 2024

The Certification Notice provides actual information concerning the application(s) made by the Certification holder and the product(s) covered by the Certificate(s) as well as information regarding the examination and assessment activities performed by the Certification Body related to the performed Conformity Assessment Procedure(s) and the reference to the relevant documentation.

1 CERTIFICATION HOLDER

Beijing Synapsor Artificial Intelligence Co., Ltd.
Room S408, Floor 4, Building 7, Yard 10, Xibeiwang East Road,
Haidian District,
100193 Beijing
China
SRN ID.: CN-MF-000022964

2 APPLICATION(S)

The application(s) made by the Certification holder under the provisions of below-mentioned standard(s) conform(s) to the applicable provisions of the EC/UK-Directive/regulation(s), ISO standards and/or other regulations and include(s) the documentation and the relevant undertakings and/or statements required:

The following applications are under the accreditation of **DEKRA Certification B.V.:**

- **MDR:** REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and amended by REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

- **QMS standards:** EN ISO 13485:2016 (RvA).

3 CERTIFICATION STRUCTURE

3.1 CE Certification Structure

To cover all products included in the application(s), the following scope(s) for the CE-certificates are defined:

MDR

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
6132038CE01	**BLOOD SUGAR MONITORING SYSTEMS (Z12040115, Class IIb)** **Basic UDI-DI:** 69751306101UG **Device Name:** Syai® Continuous Glucose Monitoring System	MDR, Annex IX	Class IIb Rule 8, 10	Drafted DoC # TCF-CGM-4.3, rev. A/0

The products described in the above mentioned certification holder's "Declaration of Conformity" form an integral part of this Certification Notice.

4 QUALITY SYSTEM STRUCTURE

The assessment of the applied Quality System of the certification holder is primarily covered by the assessment based on the standards identified in the table below.

QMS certificates issued by DEKRA Certification:

Certificate number	Scope of certificate	QS Standard(s) (incl. Accreditation Authority)
6132037	Design and Development, Manufacture and Distribution of Continuous Glucose Monitoring Systems	EN ISO 13485:2016 (RvA)

Exclusions:	NA
Non-Applications:	7.5.3 installation activities 7.5.9.2 Particular requirements for implantable medical devices

5 ADDITIONAL LOCATION(S)

The relevant additional sites covered by a Quality System under responsibility of the Certification holder are identified in the table below.

Certificate number	Location	Certification scope / Activity
6132037	Beijing Synapsor Artificial Intelligence Co., Ltd. Floor 2, Building 3, Yard 58, Jinghai Fifth Road, Beijing Economic and Technological	Manufacture of Continuous Glucose Monitoring Systems

	Development Zone (Tongzhou), 101111 Beijing, China	

6 SUBCONTRACTED REGULATORY REPRESENTATION

The Certification Holder's subcontracted regulatory representation, covered by a QA/RA agreement, is identified in the table below.

Company name / city / country	Type of service to Certification holder
Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany	EU Authorized representative

7 SUBCONTRACTOR(S) / OUTSOURCING

The critical subcontractors performing processes, which results are not or cannot be verified by the Certification holder and/or the critical contractors to which relevant processes have been outsourced are identified in the table below:

Company name / address	Type of service to Certification holder	QS standard and name certifier	Certificate number and expiry date
Beijing Atom Hightech Jinhui Radiation Technology Application Co., Ltd. No. 188 Yanfang Industrial Park, Yancun Fangshan District, 102413 Beijing, P.R. China	Provision of irradiation sterilization of Glucose sensor	(EN) ISO 13485:2016, ISO11137, issued by TÜV SÜD Product Service GmbH.	Q8054870 0008 rev. 00, SUP 054870 0009, Rev.00 expired on 2024-05-30

8 EVALUATION OF TECHNICAL DOCUMENTATION

The examination and assessment of the Design Dossier(s), verification or examination/assessment of the technical documentation and/or the verification of manufactured products / batches are identified in the table below.

Brief notification description	Reference to client's MAF or NoC	Regulation/Directive & Conformity Assessment Route	Applies to following certificate number(s) and CN version	Report or review letter (+ date of approval)
Initial MDR TD assessment review for Continuous	MAF (dated on 20 May 2022)	MDR, Annex IX	6132038CE01 6132037CN02	6132038-TDR01-R0 (11 April 2024)

Glucose Monitoring Systems				

Based on the results of the activities performed, it has been determined that the design of the product(s) (DE/TD/TE examination) or the product(s), including the variant(s) (other conformity assessment routes), stated in this Certification Notice, fulfill(s) the relevant regulations.

9 EVALUATION OF QUALITY MANAGEMENT SYSTEM

The applied Quality System has been assessed to determine whether this Quality System complies with the applicable requirements of the EC/UK-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice. This is described in the audit report(s) mentioned in the table below.

Activity (audit/substantial change) brief description	**Reference to client's MAF or NoC or n/a**	**Regulation/Directive & Conformity Assessment Route**	**Applies to following certificate number(s) and CN version**	**Report or review letter (+ date of approval)**
Stage 1 audit in accordance with EN ISO 13485 (March 2023)	MAF (dated on 20 May 2022)	N/A	6132037 6132037CN01	6132037-AR01-R1 (approved on 13 September 2023)
Initial Stage 2 audit in accordance with EN ISO 13485, MDR Annex IX (May 2023)	MAF (dated on 20 May 2022)	MDR, Annex IX	6132037 6132038CE01 6132037CN02	6132037-AR02-R1 (approved on 11 April 2024)

DEKRA Certification has determined by examination and assessment that the applied Quality System(s) comply with the relevant requirements in accordance with the applied conformity assessment procedure(s) of the EC/UK-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice.

10 CONCLUSION

10.1 Conclusion DEKRA Certification B.V.

DEKRA Certification B.V. declares, based on the results of the examination and assessment activities performed, that the applied Conformity Assessment Procedures are executed by the Certification holder in accordance with the provisions of the EC-Directive/regulation, ISO standards and/or other regulations.

With regards to CE certification, the compliance of the products concerned with the Essential Requirements/GSPR (Annex I) of the EC-Directive/regulation remain, according to the provisions of this Directive/regulation, at all times the full responsibility of the Certification holder.

The following certificates will be issued under the conditions of the signed certification agreement with DEKRA Certification B.V. CA-22-7471471:

MDR

Certificate number	Initial date	Renewal date	Revision date*	Expiry date
6132038CE01	11 April 2024	-	-	1 April 2029

ISO

Certificate number	Standard	Initial date	Effective date*	Expiry date
6132037	EN ISO 13485:2016 (RvA)	13 September 2023	13 September 2023	1 September 2026

*** C for certificate, A for addendum**

The right to use the DEKRA Certification B.V. Identification Number **0344**, as stated in the relevant Certificate(s) and under the conditions of said Agreement, only applies to the CE-Certified product(s) covered by this Certification Notice.

11 April 2024

Signature of Certification Manager

Date

DEKRA Certification B.V, Arnhem, The Netherlands