Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen Envisen Industry Co., Ltd.
Block 1, Room 201,301,401, 40 Jianlong Street,
Baoan Community, Yuanshan Town, Longgang District,
Shenzhen, 518115, Guangdong,
P.R. China

Contact

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Mail: medical-products@de.tuv.com

Date May 11, 2024

Notified Body Confirmation Letter
Reference. : ENVIS_PLA_2024-03-28; order#10924274

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Shenzhen Envisen Industry Co., Ltd.
Block 1, Room 201,301,401, 40 Jianlong Street,
Baoan Community, Yuanshan Town, Longgang District,
Shenzhen, 518115, Guangdong,
P.R. China
SRN Number (if available): CN-MF-000010838

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Samuel Qin

Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Re-usable Temperature Probe **Basic UDI-DI:** 697144961TPRSTE	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Rectal/Oesophageal **Basic UDI-DI:** 697144961TPRGSN	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Disposable Temperature Probe **Basic UDI-DI:** 697144961TPDSS4	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Rectal/Oesophageal **Basic UDI-DI:** 697144961TPDGRC	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
			NB#0197
Breathing Circuit **Basic UDI-DI:** 697144961BCQRU	Class IIa	N/A	Certificate # HD 60147402 0001 NB#0197
Breathing Circuit **Basic UDI-DI:** 697144961BCCQY	Class IIa	N/A	Certificate # HD 60147402 0001 NB#0197
Breathing Circuit **Basic UDI-DI:** 697144961BCER4	Class IIa	N/A	Certificate # HD 60147402 0001 NB#0197
Pulse Oximeter **Basic UDI-DI:** 697144961POHUL	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Pulse Oximeter **Basic UDI-DI:** 697144961POFUG	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Disposable Oximeter Probes **Basic UDI-DI:** 697144961OPDUA	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Re-usable Oximeter Probes **Basic UDI-DI:** 697144961OPRCRB	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Re-usable Oximeter Probes **Basic UDI-DI:** 697144961OPRTSD	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001 NB#0197
Re-usable Oximeter Probes	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60147402 0001

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 697144961OPRWSK			NB#0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-11	ENVIS_CL607_2024-05-11	Initial issue

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60147402 0001

Report No.: 17023744 015

Manufacturer:

Shenzhen Envisen Industry Co., Ltd.
Block 1, Room 201, 301, 401, 40 Jianlong Street
Baoan Community, Yuanshan Town
Longgang District
Shenzhen
518115 Guangdong
P.R. China

Products:

Oximeter Probes, Temperature Probes, Breathing Circuits, Pulse Oximeters

Replaces Approval, Registration No.: HD 60144567 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-06-23

Date: 2020-06-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.