Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

YASEE BioMedical Inc.
No.9 Xiuyuan Road,
High-tech Industrial Development Zone,
Qingdao City,
266000 Shandong
P.R. China

Contact

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Date May 23, 2025

Notified Body Confirmation Letter
Reference. : YASEE_PDQ1_2025-04-18, order no. # 190165420

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) 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 IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

YASEE BioMedical Inc.
No.9 Xiuyuan Road,
High-tech Industrial Development Zone,
Qingdao City,
266000 Shandong
P.R. China
SRN Number: CN-MF-000037011

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 IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive 98/79/EC. Table 2 identifies the devices for which an IVDR 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 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence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 54 of IVDR or Article 92 of the IVDR respectively, by July 9, 2024 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 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body

Dr. Volker Schlüter
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 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	**IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the IVDR device is a substitute device, identification of the corresponding IVDD device**	**IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification**
Device name: Blood Glucose Meter Basic UDI-DI: 697196956CHD 697196956GLMXZ	Class C, self-testing	Blood Glucose Meters	Certificate # HL 2147514-1 NB#0197
Device name: Blood Glucose Test Strip Basic UDI-DI: 697196956AH9 697196956GLSYD	Class C, self-testing	Blood Glucose Test Strips	Certificate # HL 2147514-1 NB#0197
Device name: Glucose Control Solution Basic UDI-DI: 697196956GCS01R4 697196956GCS06RE	Class C, self-testing	Blood Glucose Control Solutions	Certificate # HL 2147514-1 NB#0197

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Device name: Blood Glucose Monitoring System Basic UDI-DI: 697196956ABGMSRM 697196956GBGMSTP	Class C, self-testing	Blood Glucose Monitoring Systems	Certificate # HL 2147514-1 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 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025/05/23	Order No. 190165420	Initial issue