

TÜV Rheinland LGA Products GmbH • 51105 Köln

*Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park,
Xiamen, 361021 Fujian
P.R. China*

Contact

Tel. **+49 911 655-5225**
Mail: medical-products@de.tuv.com

Date May 22, 2026

Notified Body Confirmation Letter

Reference. : BOSON_PDQ0_2026-01-20, order no. 10927725

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:

Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park,
Xiamen, 361021 Fujian
P.R. China
SRN Number (if available): CN-MF-000001096

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issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence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.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Kimmo Fuller

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



Marta Trzpil

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
None	-	-	-

Table 2: Devices covered by this letter and for which the NB is NOT 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
2019-nCoV IgG/IgM Combo Test Basic UDI-DI: 692196371876K7	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Chikungunya IgG/IgM Combo Test Basic UDI-DI: 692196371877K9	Class B	N/A	N/A - Device did not require a Notified Body certificate
Zika Virus IgG/IgM Combo Test Basic UDI-DI: 692196371604J4	Class C	N/A	N/A - Device did not require a Notified Body certificate
K2 Test Basic UDI-DI: 692196371878KB	Class C	N/A	N/A - Device did not require a Notified Body certificate
Methylphenidate Test Basic UDI-DI: 692196371879KD	Class C	N/A	N/A - Device did not require a Notified Body certificate
Methaqualone Test Basic UDI-DI: 692196371880JW	Class C	N/A	N/A - Device did not require a Notified Body certificate
Adenovirus Antigen Test Basic UDI-DI: 692196371881JY	Class B	N/A	N/A - Device did not require a Notified Body certificate
S.typhi/paratyphi Antigen Duo Test Basic UDI-DI: 692196371882K2	Class C	N/A	N/A - Device did not require a Notified Body certificate
Dengue NS1 Antigen Test Basic UDI-DI: 692196371599K4	Class C	N/A	N/A - Device did not require a Notified Body certificate
Influenza A Test Basic UDI-DI: 692196371605J6	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Amphetamine Test Basic UDI-DI: 692196371883K4	Class C	N/A	N/A - Device did not require a Notified Body certificate
Benzodiazepine Test Basic UDI-DI: 692196371884K6	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cocaine Test Basic UDI-DI: 692196371885K8	Class C	N/A	N/A - Device did not require a Notified Body certificate
Methamphetamine Test Basic UDI-DI: 692196371886KA	Class C	N/A	N/A - Device did not require a Notified Body certificate
THC Test Basic UDI-DI: 692196371887KC	Class C	N/A	N/A - Device did not require a Notified Body certificate
Opiate Test Basic UDI-DI: 692196371888KE	Class C	N/A	N/A - Device did not require a Notified Body certificate
Methadone Test Basic UDI-DI: 692196371889KG	Class C	N/A	N/A - Device did not require a Notified Body certificate
Drugs of Abuse Test Cup Basic UDI-DI: 692196371890JZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Drugs of Abuse Panel Test Basic UDI-DI: 692196371891K3	Class C	N/A	N/A - Device did not require a Notified Body certificate
Fecal Occult Blood Test Basic UDI-DI: 692196371613J5	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Adeno/Rota Virus Antigen Combo Test Basic UDI-DI: 692196371892K5	Class B	N/A	N/A - Device did not require a Notified Body certificate
Influenza A +B Test Basic UDI-DI: 692196371606J8	Class B	N/A	N/A - Device did not require a Notified Body certificate
Strep A Test Basic UDI-DI: 692196371893K7	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rapid SARS-CoV-2 Antigen Test Card Basic UDI-DI: 692196371787K7	Class B	N/A	N/A - Device did not require a Notified Body certificate
Syphilis Antibody Test Basic UDI-DI: 692196371894K9	Class C	N/A	N/A - Device did not require a Notified Body certificate
Malaria Antigen Test Basic UDI-DI: 692196371895KB	Class C	N/A	N/A - Device did not require a Notified Body certificate
Dengue IgG/IgM Combo Test Basic UDI-DI: 692196371896KD	Class B	N/A	N/A - Device did not require a Notified Body certificate
Dengue NS1 Antigen and IgG/IgM Duo Panel Test Basic UDI-DI: 692196371897KF	Class C	N/A	N/A - Device did not require a Notified Body certificate
C-reactive Protein Test Basic UDI-DI: 692196371898KH	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
HCG Pregnancy Test Basic UDI-DI: 692196371899KK	Class B	N/A	N/A - Device did not require a Notified Body certificate
LH Test Basic UDI-DI: 692196371900JB	Class B	N/A	N/A - Device did not require a Notified Body certificate
Troponin I Test Basic UDI-DI: 692196371901JD	Class C	N/A	N/A - Device did not require a Notified Body certificate
Myoglobin Test Basic UDI-DI: 692196371902JF	Class C	N/A	N/A - Device did not require a Notified Body certificate
CK-MB Test Basic UDI-DI: 692196371903JH	Class C	N/A	N/A - Device did not require a Notified Body certificate
D-Dimer Test Basic UDI-DI: 692196371904JK	Class C	N/A	N/A - Device did not require a Notified Body certificate
H.Pylori Antigen Test Basic UDI-DI: 692196371600HU	Class B	N/A	N/A - Device did not require a Notified Body certificate
H.Pylori Antibody Test Basic UDI-DI: 692196371905JM	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rotavirus Antigen Test Basic UDI-DI: 692196371906JP	Class B	N/A	N/A - Device did not require a Notified Body certificate
V.Cholerae O1/O139 Duo Test Basic UDI-DI: 692196371907JR	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Salmonella typhi Antigen Test Basic UDI-DI: 692196371908JT	Class C	N/A	N/A - Device did not require a Notified Body certificate
Salmonella typhi IgG/IgM Combo Test Basic UDI-DI: 692196371601HW	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rickettsia IgG/IgM Combo Test Basic UDI-DI: 692196371909JV	Class B	N/A	N/A - Device did not require a Notified Body certificate
Tuberculosis Test Basic UDI-DI: 692196371910JE	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cardiac Panel Test Basic UDI-DI: 692196371911JG	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid SARS-CoV-2/Influenza A+B Antigen Duo Test Card Basic UDI-DI: 692196371607JA	Class B	N/A	N/A - Device did not require a Notified Body certificate
Barbiturate Test Basic UDI-DI: 692196371912JJ	Class C	N/A	N/A - Device did not require a Notified Body certificate
TCA Test Basic UDI-DI: 692196371913JL	Class C	N/A	N/A - Device did not require a Notified Body certificate
Buprenorphine Test Basic UDI-DI: 692196371914JN	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
EDDP Test Basic UDI-DI: 692196371915JQ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Oxycodone Test Basic UDI-DI: 692196371916JS	Class C	N/A	N/A - Device did not require a Notified Body certificate
Phencyclidine Test Basic UDI-DI: 692196371917JU	Class C	N/A	N/A - Device did not require a Notified Body certificate
Propoxyphene Test Basic UDI-DI: 692196371918JW	Class C	N/A	N/A - Device did not require a Notified Body certificate
Tramadol Test Basic UDI-DI: 692196371919JY	Class C	N/A	N/A - Device did not require a Notified Body certificate
Ketamine Test Basic UDI-DI: 692196371920JH	Class C	N/A	N/A - Device did not require a Notified Body certificate
Fentanyl Test Basic UDI-DI: 692196371921JK	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cotinine Test Basic UDI-DI: 692196371922JM	Class C	N/A	N/A - Device did not require a Notified Body certificate
Clonazepam Test Basic UDI-DI: 692196371923JP	Class C	N/A	N/A - Device did not require a Notified Body certificate
MDMA Test Basic UDI-DI: 692196371924JR	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Urine Alcohol Test Basic UDI-DI: 692196371925JT	Class C	N/A	N/A - Device did not require a Notified Body certificate
Saliva Alcohol Test Basic UDI-DI: 692196371926JV	Class C	N/A	N/A - Device did not require a Notified Body certificate
V.Cholerae O1 Test Basic UDI-DI: 692196371602HY	Class C	N/A	N/A - Device did not require a Notified Body certificate
V.Cholerae O139 Test Basic UDI-DI: 692196371603J2	Class C	N/A	N/A - Device did not require a Notified Body certificate
NT-proBNP Test Basic UDI-DI: 692196371927JX	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cystatin C Test Basic UDI-DI: 692196371928JZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
β2-Microglobulin Test Basic UDI-DI: 692196371929K3	Class C	N/A	N/A - Device did not require a Notified Body certificate
Serum Amyloid A Test Basic UDI-DI: 692196371930JL	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rheumatoid Factor Test Basic UDI-DI: 692196371931JN	Class C	N/A	N/A - Device did not require a Notified Body certificate
Transferrin Test Basic UDI-DI: 692196371932JQ	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Hemoglobin/Transferrin Panel Test Basic UDI-DI: 692196371933JS	Class C	N/A	N/A - Device did not require a Notified Body certificate
SARS-CoV-2 Neutralizing Antibody Test Card Basic UDI-DI: 692196371934JU	Class B	N/A	N/A - Device did not require a Notified Body certificate
Anti-SARS-CoV-2 S Protein Antibody Test Card Basic UDI-DI: 692196371935JW	Class B	N/A	N/A - Device did not require a Notified Body certificate
SARS-CoV-2 Neutralizing Antibody Quantitative Test Basic UDI-DI: 692196371936JY	Class B	N/A	N/A - Device did not require a Notified Body certificate
Anti-SARS-CoV-2 S Protein Antibody Quantitative Test Basic UDI-DI: 692196371937K2	Class B	N/A	N/A - Device did not require a Notified Body certificate
SARS-CoV-2 Antigen Saliva Test Card Basic UDI-DI: 692196371938K4	Class B	N/A	N/A - Device did not require a Notified Body certificate
AFP Quantitative Test Basic UDI-DI: 692196371939K6	Class C	N/A	N/A - Device did not require a Notified Body certificate
CEA Quantitative Test Basic UDI-DI: 692196371940JP	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
CEA/AFP Quantitative Test Basic UDI-DI: 692196371941JR	Class C	N/A	N/A - Device did not require a Notified Body certificate
Serum Amyloid A Quantitative Test Basic UDI-DI: 692196371942JT	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cystatin C Quantitative Test Basic UDI-DI: 692196371943JV	Class C	N/A	N/A - Device did not require a Notified Body certificate
C-reactive Protein Quantitative Test Basic UDI-DI: 692196371944JX	Class C	N/A	N/A - Device did not require a Notified Body certificate
D-Dimer Quantitative Test Basic UDI-DI: 692196371945JZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Interleukin-6 Quantitative Test Basic UDI-DI: 692196371946K3	Class C	N/A	N/A - Device did not require a Notified Body certificate
NT-proBNP Quantitative Test Basic UDI-DI: 692196371947K5	Class C	N/A	N/A - Device did not require a Notified Body certificate
Procalcitonin Quantitative Test Basic UDI-DI: 692196371948K7	Class C	N/A	N/A - Device did not require a Notified Body certificate
Troponin I Quantitative Test Basic UDI-DI:	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
692196371949K9			
Troponin T Quantitative Test Basic UDI-DI: 692196371950JS	Class C	N/A	N/A - Device did not require a Notified Body certificate
AFP Test Basic UDI-DI: 692196371951JU	Class C	N/A	N/A - Device did not require a Notified Body certificate
CEA Test Basic UDI-DI: 692196371952JW	Class C	N/A	N/A - Device did not require a Notified Body certificate
HAV Test Basic UDI-DI: 692196371953JY	Class B	N/A	N/A - Device did not require a Notified Body certificate
HEV Test Basic UDI-DI: 692196371954K2	Class C	N/A	N/A - Device did not require a Notified Body certificate
Legionella Antigen Test Basic UDI-DI: 692196371956K6	Class C	N/A	N/A - Device did not require a Notified Body certificate
Respiratory Syncytial Virus Antigen Test Basic UDI-DI: 692196371790JU	Class B	N/A	N/A - Device did not require a Notified Body certificate
SARS-CoV-2/Flu A+B/RSV Antigen Test Card Basic UDI-DI: 692196371789KB	Class B	N/A	N/A - Device did not require a Notified Body certificate
SARS-CoV-2/Flu A+B/RSV/ADV Antigen Test Card Basic UDI-DI: 692196371957K8	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Monkeypox Virus IgG/IgM Combo Test Basic UDI-DI: 692196371958KA	Class C	N/A	N/A - Device did not require a Notified Body certificate
Monkeypox Virus Antigen Test Basic UDI-DI: 692196371959KC	Class C	N/A	N/A - Device did not require a Notified Body certificate
Alpha-Fetoprotein assay (CLIA) Basic UDI-DI: 692196372170HX	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cancer Embryo Antigen assay (CLIA) Basic UDI-DI: 692196372171HZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Carbohydrate Antigen 19-9 assay (CLIA) Basic UDI-DI: 692196372172J3	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cancer Antigen 15-3 assay (CLIA) Basic UDI-DI: 692196372173J5	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cancer Antigen 125 assay (CLIA) Basic UDI-DI: 692196372174J7	Class C	N/A	N/A - Device did not require a Notified Body certificate
Pepsinogen I assay (CLIA) Basic UDI-DI: 692196372175J9	Class B	N/A	N/A - Device did not require a Notified Body certificate
Pepsinogen II assay (CLIA) Basic UDI-DI:	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
692196372176JB			
Gastrin-17 assay (CLIA) Basic UDI-DI: 692196372177JD	Class B	N/A	N/A - Device did not require a Notified Body certificate
Carbohydrate Antigen 242 assay (CLIA) Basic UDI-DI: 692196372178JF	Class C	N/A	N/A - Device did not require a Notified Body certificate
Carbohydrate Antigen 72-4 assay (CLIA) Basic UDI-DI: 692196372179JH	Class C	N/A	N/A - Device did not require a Notified Body certificate
Squamous Cell Carcinoma assay (CLIA) Basic UDI-DI: 692196372180J2	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cytokeratin 19 Fragment 21-1 assay (CLIA) Basic UDI-DI: 692196372181J4	Class C	N/A	N/A - Device did not require a Notified Body certificate
Neuron-Specific Enolase assay (CLIA) Basic UDI-DI: 692196372182J6	Class C	N/A	N/A - Device did not require a Notified Body certificate
Progastrin-Releasing Peptide assay (CLIA) Basic UDI-DI: 692196372183J8	Class C	N/A	N/A - Device did not require a Notified Body certificate
Treponema Pallidum Antibody assay (CLIA) Basic UDI-DI: 692196372184JA	Class C	N/A	N/A - Device did not require a Notified Body certificate
Helicobacter Pylori IgG assay (CLIA)	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Basic UDI-DI: 692196372185JC			
Progesterone assay (CLIA) Basic UDI-DI: 692196372186JE	Class B	N/A	N/A - Device did not require a Notified Body certificate
Testosterone assay (CLIA) Basic UDI-DI: 692196372187JG	Class B	N/A	N/A - Device did not require a Notified Body certificate
Estradiol assay (CLIA) Basic UDI-DI: 692196372188JJ	Class B	N/A	N/A - Device did not require a Notified Body certificate
Follicle-Stimulating Hormone assay (CLIA) Basic UDI-DI: 692196372189JL	Class B	N/A	N/A - Device did not require a Notified Body certificate
Luteinizing Hormone assay (CLIA) Basic UDI-DI: 692196372190J5	Class B	N/A	N/A - Device did not require a Notified Body certificate
Prolactin (PRL) assay (CLIA) Basic UDI-DI: 692196372191J7	Class B	N/A	N/A - Device did not require a Notified Body certificate
Human Chorionic Gonadotropin assay (CLIA) Basic UDI-DI: 692196372192J9	Class C	N/A	N/A - Device did not require a Notified Body certificate
Anti-Müllerian Hormone assay (CLIA) Basic UDI-DI: 692196372193JB	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Insulin assay (CLIA) Basic UDI-DI: 692196372194JD	Class B	N/A	N/A - Device did not require a Notified Body certificate
C-Peptide assay (CLIA) Basic UDI-DI: 692196372195JF	Class B	N/A	N/A - Device did not require a Notified Body certificate
Adiponectin assay (CLIA) Basic UDI-DI: 692196372196JH	Class C	N/A	N/A - Device did not require a Notified Body certificate
HbA1c assay (CLIA) Basic UDI-DI: 692196372197JK	Class C	N/A	N/A - Device did not require a Notified Body certificate
Thyroid Stimulating Hormone assay (CLIA) Basic UDI-DI: 692196372198JM	Class B	N/A	N/A - Device did not require a Notified Body certificate
Free Triiodothyronine assay (CLIA) Basic UDI-DI: 692196372199JP	Class B	N/A	N/A - Device did not require a Notified Body certificate
Free Thyroxine assay (CLIA) Basic UDI-DI: 692196372200HF	Class B	N/A	N/A - Device did not require a Notified Body certificate
Total Triiodothyronine assay (CLIA) Basic UDI-DI: 692196372201HH	Class B	N/A	N/A - Device did not require a Notified Body certificate
Total Thyroxine assay (CLIA) Basic UDI-DI: 692196372202HK	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Thyroid-Globulin Antibody assay (CLIA) Basic UDI-DI: 692196372203HM	Class B	N/A	N/A - Device did not require a Notified Body certificate
Thyroid-Peroxidase Antibody assay (CLIA) Basic UDI-DI: 692196372204HP	Class B	N/A	N/A - Device did not require a Notified Body certificate
Thyroid Globulin assay (CLIA) Basic UDI-DI: 692196372205HR	Class B	N/A	N/A - Device did not require a Notified Body certificate
Thyrotropin Receptor Antibody assay (CLIA) Basic UDI-DI: 692196372206HT	Class B	N/A	N/A - Device did not require a Notified Body certificate
Hypersensitive Troponin I assay (CLIA) Basic UDI-DI: 692196372207HV	Class C	N/A	N/A - Device did not require a Notified Body certificate
Hypersensitive Troponin T assay (CLIA) Basic UDI-DI: 692196372208HX	Class C	N/A	N/A - Device did not require a Notified Body certificate
NT-proBNP assay (CLIA) Basic UDI-DI: 692196372209HZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Creatine Kinase-MB assay (CLIA) Basic UDI-DI: 692196372210HJ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Myoglobin assay (CLIA) Basic UDI-DI: 692196372211HL	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Procalcitonin assay (CLIA) Basic UDI-DI: 692196372212HN	Class C	N/A	N/A - Device did not require a Notified Body certificate
Hypersensitive C-reactive Protein assay (CLIA) Basic UDI-DI: 692196372213HQ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Serum Amyloid A assay (CLIA) Basic UDI-DI: 692196372214HS	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cortisol assay (CLIA) Basic UDI-DI: 692196372215HU	Class B	N/A	N/A - Device did not require a Notified Body certificate
IGFBP-3 assay (CLIA) Basic UDI-DI: 692196372216HW	Class B	N/A	N/A - Device did not require a Notified Body certificate
IGF-1 assay (CLIA) Basic UDI-DI: 692196372217HY	Class B	N/A	N/A - Device did not require a Notified Body certificate
Calcitonin assay (CLIA) Basic UDI-DI: 692196372218J2	Class C	N/A	N/A - Device did not require a Notified Body certificate
25-Hydroxy Vitamin D assay (CLIA) Basic UDI-DI: 692196372219J4	Class B	N/A	N/A - Device did not require a Notified Body certificate
Ferritin assay (CLIA) Basic UDI-DI: 692196372220HM	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Vitamin B12 assay (CLIA) Basic UDI-DI: 692196372221HP	Class B	N/A	N/A - Device did not require a Notified Body certificate
Folate assay (CLIA) Basic UDI-DI: 692196372222HR	Class B	N/A	N/A - Device did not require a Notified Body certificate
Thrombomodulin assay (CLIA) Basic UDI-DI: 692196372223HT	Class C	N/A	N/A - Device did not require a Notified Body certificate
PIC assay (CLIA) Basic UDI-DI: 692196372224HV	Class C	N/A	N/A - Device did not require a Notified Body certificate
Thrombin-Antithrombin III Complex assay (CLIA) Basic UDI-DI: 692196372225HX	Class C	N/A	N/A - Device did not require a Notified Body certificate
D-Dimer assay (CLIA) Basic UDI-DI: 692196372226HZ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Immunoglobulin E assay (CLIA) Basic UDI-DI: 692196372227J3	Class C	N/A	N/A - Device did not require a Notified Body certificate
Anti-CCP assay (CLIA) Basic UDI-DI: 692196372228J5	Class C	N/A	N/A - Device did not require a Notified Body certificate
β2-Microglobulin assay (CLIA) Basic UDI-DI: 692196372229J7	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Alpha-Fetoprotein Test (FIA) Basic UDI-DI: 692196372230HQ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Cancer Embryo Antigen Test (FIA) Basic UDI-DI: 692196372231HS	Class C	N/A	N/A - Device did not require a Notified Body certificate
C-Reactive Protein Test (FIA) Basic UDI-DI: 692196372232HU	Class C	N/A	N/A - Device did not require a Notified Body certificate
Serum Amyloid A Test (FIA) Basic UDI-DI: 692196372233HW	Class C	N/A	N/A - Device did not require a Notified Body certificate
Procalcitonin Test (FIA) Basic UDI-DI: 692196372234HY	Class C	N/A	N/A - Device did not require a Notified Body certificate
Interleukin-6 Test (FIA) Basic UDI-DI: 692196372235J2	Class C	N/A	N/A - Device did not require a Notified Body certificate
Anti-Streptolysin O Test (FIA) Basic UDI-DI: 692196372236J4	Class B	N/A	N/A - Device did not require a Notified Body certificate
Dengue NS1 Antigen Test (FIA) Basic UDI-DI: 692196372237J6	Class C	N/A	N/A - Device did not require a Notified Body certificate
Dengue IgG/IgM Combo Test (FIA) Basic UDI-DI: 692196372238J8	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
SARS-CoV-2 Antigen Test (FIA) Basic UDI-DI: 692196372239JA	Class B	N/A	N/A - Device did not require a Notified Body certificate
Influenza A + B Antigen Test (FIA) Basic UDI-DI: 692196372240HT	Class B	N/A	N/A - Device did not require a Notified Body certificate
Respiratory Syncytial Virus Antigen Test (FIA) Basic UDI-DI: 692196372241HV	Class B	N/A	N/A - Device did not require a Notified Body certificate
Cystatin C Test (FIA) Basic UDI-DI: 692196372242HX	Class C	N/A	N/A - Device did not require a Notified Body certificate
Microalbumin Test (FIA) Basic UDI-DI: 692196372243HZ	Class B	N/A	N/A - Device did not require a Notified Body certificate
25-Hydroxy Vitamin D Test (FIA) Basic UDI-DI: 692196372244J3	Class B	N/A	N/A - Device did not require a Notified Body certificate
Troponin I Test (FIA) Basic UDI-DI: 692196372245J5	Class C	N/A	N/A - Device did not require a Notified Body certificate
Troponin T Test (FIA) Basic UDI-DI: 692196372246J7	Class C	N/A	N/A - Device did not require a Notified Body certificate
NT-proBNP Test (FIA) Basic UDI-DI: 692196372247J9	Class C	N/A	N/A - Device did not require a Notified Body certificate
B-type Natriuretic Peptide Test (FIA)	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Basic UDI-DI: 692196372248JB			
D-Dimer Test (FIA) Basic UDI-DI: 692196372249JD	Class C	N/A	N/A - Device did not require a Notified Body certificate
Myeloperoxidase Test (FIA) Basic UDI-DI: 692196372250HW	Class C	N/A	N/A - Device did not require a Notified Body certificate
sST2 Test (FIA) Basic UDI-DI: 692196372251HY	Class C	N/A	N/A - Device did not require a Notified Body certificate
Creatine Kinase-MB Test (FIA) Basic UDI-DI: 692196372252J2	Class C	N/A	N/A - Device did not require a Notified Body certificate
Myoglobin Test (FIA) Basic UDI-DI: 692196372253J4	Class C	N/A	N/A - Device did not require a Notified Body certificate
cTnI /CK-MB/MYO Panel Test (FIA) Basic UDI-DI: 692196372254J6	Class C	N/A	N/A - Device did not require a Notified Body certificate
HbA1C Test (FIA) Basic UDI-DI: 692196372255J8	Class C	N/A	N/A - Device did not require a Notified Body certificate
Thyroid Stimulating Hormone Test (FIA) Basic UDI-DI: 692196372256JA	Class B	N/A	N/A - Device did not require a Notified Body certificate
Free Triiodothyronine Test (FIA) Basic UDI-DI: 692196372257JC	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Free Thyroxine Test (FIA) Basic UDI-DI: 692196372258JE	Class B	N/A	N/A - Device did not require a Notified Body certificate
Total Triiodothyronine Test (FIA) Basic UDI-DI: 692196372259JG	Class B	N/A	N/A - Device did not require a Notified Body certificate
Total Thyroxine Test (FIA) Basic UDI-DI: 692196372260HZ	Class B	N/A	N/A - Device did not require a Notified Body certificate
Luteinizing Hormone Test (FIA) Basic UDI-DI: 692196372261J3	Class B	N/A	N/A - Device did not require a Notified Body certificate
Progesterone Test (FIA) Basic UDI-DI: 692196372262J5	Class B	N/A	N/A - Device did not require a Notified Body certificate
Prolactin Test (FIA) Basic UDI-DI: 692196372263J7	Class B	N/A	N/A - Device did not require a Notified Body certificate
Testosterone Test (FIA) Basic UDI-DI: 692196372264J9	Class B	N/A	N/A - Device did not require a Notified Body certificate
Ferritin Test (FIA) Basic UDI-DI: 692196372265JB	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rapid Leptospira IgG/IgM Combo Test Basic UDI-DI: 692196372266JD	Class B	N/A	N/A - Device did not require a Notified Body certificate

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
Rapid Flu A+B/RSV/ADV Antigen Test Card Basic UDI-DI: 692196372267JF	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rapid Flu A+B/RSV Antigen Test Card Basic UDI-DI: 692196372268JH	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rapid Mycoplasma Pneumoniae Antigen Test Basic UDI-DI: 692196372269JK	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid HPIV Antigen Test Basic UDI-DI: 692196372270J4	Class B	N/A	N/A - Device did not require a Notified Body certificate
Rapid HSV I&II IgG/IgM Combo Test Basic UDI-DI: 692196372271J6	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Rubella IgG/IgM Combo Test Basic UDI-DI: 692196372272J8	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Anti-CCP Antibody Test Basic UDI-DI: 692196372273JA	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Carisoprodol Test Basic UDI-DI: 692196372274JC	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Pregabalin Test Basic UDI-DI: 692196372275JE	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Rapid Ethyl Glucuronide Test Basic UDI-DI: 692196372276JG	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Methcathinone Test Basic UDI-DI: 692196372277JJ	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Kratom Test Basic UDI-DI: 692196372278JL	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid AB-PINACA Test Basic UDI-DI: 692196372279JN	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid UR-144 Test Basic UDI-DI: 692196372280J7	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid MDPV Test Basic UDI-DI: 692196372281J9	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Xylazine Test Basic UDI-DI: 692196372282JB	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid α-PVP Test Basic UDI-DI: 692196372283JD	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Etomidate Test Basic UDI-DI: 692196372284JF	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Heroin Test Basic UDI-DI: 692196372285JH	Class C	N/A	N/A - Device did not require a Notified Body certificate

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
Rapid Codeine Test Basic UDI-DI: 692196372286JK	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Dextromethorphan Test Basic UDI-DI: 692196372287JM	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Norfentanyl Test Basic UDI-DI: 692196372288JP	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Diphenoxylate Test Basic UDI-DI: 692196372289JR	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Dimethyltryptamine Test Basic UDI-DI: 692196372290JA	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Gabapentin Test Basic UDI-DI: 692196372291JC	Class C	N/A	N/A - Device did not require a Notified Body certificate
Rapid Zolpidem Test Basic UDI-DI: 692196372292JE	Class C	N/A	N/A - Device did not require a Notified Body certificate
Hantavirus IgG/IgM Test Basic UDI-DI: 692196371955K4	Class C	N/A	N/A - Device did not require a Notified Body certificate

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-11-11	10926336	Initial issue
2026-05-22	10927725	Addition of device #97-#200 to the list