Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4,
FI-02150 ESPOO, Finland

Date: June 4, 2025

NOTIFIED BODY CONFIRMATION LETTER
Reference: Safecare Biotech (Hangzhou) Co., Ltd

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 medical devices and in vitro diagnostic medical devices.

This letter confirms that, Eurofins Electric & Electronics Finland Oy (later: Eurofins E&E Finland Oy), a notified body designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 0537 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR. Eurofins E&E Finland Oy will review the application and, if approved, sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR at the latest on 26 September 2025 with the following manufacturer:

Safecare Biotech (Hangzhou) Co., Ltd.
Building 2/203, No.18 Haishu Rd.,
Cangqian Sub-District, Yuhang District
311121 Hangzhou
CHINA
SRN Number: CN-MF-000019109

The table identifies the devices for which an IVDR application has been received and a written agreement concluded but Eurofins E&E Finland Oy has not yet taken responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79 EC. Pursuant to Article 110(3e) IVDR, until 26 September 2025 the notified body that issued the relevant certificate under the IVDD continues to be responsible for the appropriate surveillance in respect to the applicable requirements relating to devices it has certified. Alternatively, before 26 September 2025, the manufacturer can agree (‘tripartite agreement’) with the notified body that issued the IVDD certificate and with Eurofins E&E Finland Oy that the latter becomes responsible for the surveillance already before 26 September 2025. If no such agreement is signed, the notified body that issued the certificate under the IVDD will be responsible for the appropriate surveillance until 26 September, and surveillance activities will automatically transfer to Eurofins E&E Finland Oy from 26 September 2025.

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The devices covered by the formal application mentioned above are identified in the Table below.

Device name under IVDR application; Catalog number(s)	Basic UDI-DI	*IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)*	*Corresponding IVDD device(s)*	*IVDD Certificate Reference; and the NB Identification; Certificate Validity*
COVID-19 Antigen Rapid Test Kit (Swab)	697424646COV6012HZL	Class C	COVID-19 Antigen Rapid Test Kit (Swab)	Polish Centre for Testing and Certification; 1434-IVDD-460/2021 Validity: 23.09.2021 - 26.05.2025 (extended by BM.433.0218.2021.KW.MV.2024.0184)
COVID-19 & Influenza A+B Antigen Combo Rapid Test; FCO-6032H	697424646FCO6032HSG	Class C	COVID-19 & Influenza A+B Antigen Combo Rapid Test; Catalogue number: FCO-6032H	CeCert Sp. z o.o.; CeCert/063/W/E.1; Validity: 29.04.2022 – 26.05.2025
HCG Pregnancy Rapid Tests for self-testing; Strip: HCG-1011H Cassette: HCG-1012H Midstream: HCG-1013H	697424646HCG000E5	Class B	HCG Pregnancy Rapid Tests for self testing	TUV Rheinland-0197; HL2139300-1 Validity: 13.03.2022 – 26.05.2025

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,

Riikka Kylväjä
Head of Notified Body (IVDR, IVDD)
Eurofins Electric & Electronics Finland Oy
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