Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Lorne Laboratories Ltd.
Unit 1 Cutbush Park Industrial Estate, Danehill
Lower Earley Berkshire
RG6 4UT
United Kingdom

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
123789	713333265; PO 14941; PO 14942; PO 14943; PO 14944; PO 14945; 75959970	medical_devices@tuvsud.com	-	2025-02-28	1 of 6

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 123789 0002 Rev. 00

Reference: 713333265 | PO 14941 | PO 14942 | PO 14943 | PO 14944 | PO 14945 | 75959970

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) 2017/746 (in the following referenced as IVDR) as regards the transitional provisions for certain in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under IVDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following Single Registration Number (SRN)

Single Registration Number: GB-MF-000029354

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive, or these devices did not require a Notified Body certificate under Directives.

If devices covered by certificates issued under Directive Directive 98/79/EC (IVDD) that expired after 26. May 2022 and before 09. July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer 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(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR 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, are shown below:

- 31. December 2027, for devices certified under IVDD
- 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

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CLI 123789 0002

The current revision of this Confirmation Letter is valid until 2025-09-26

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-02-28

TÜV SÜD Product Service GmbH
Medical and Health Services

Agnieszka Zysko
Agnieszka Zysko (Feb 28, 2025 09:26 GMT)

Agnieszka Zysko
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Feb 28, 2025 10:20 GMT+1)

Michael Mauermeir
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	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
Not applicable	N/A	N/A	N/A

Legend: ST – self-testing; NPT – near-patient testing; CDx – companion diagnostics

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	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
Anti-D Clone 1 Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 730010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-D Clone 2 Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 710010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-D Duoclone Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 740010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-C Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 690005	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-E Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 691005	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-c Monoclonal Basic UDI-DI:	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	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
506016805RHPE Device identifiers: 692005			1434-IVDD-075/2022 NB# 1434
Anti-e Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 693005	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-C+D+E Monoclonal Basic UDI-DI: 506016805RHPE Device identifiers: 700010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-K Monoclonal Basic UDI-DI: 5060168057607C Device identifiers: 760010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-Fyb Polyclonal Basic UDI-DI: **506016805DUFFY4G** Device identifiers: **317002**	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
Anti-Fya Monoclonal Basic UDI-DI: 506016805DUFFY4G Device identifiers: 774002	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
AHG Elite Clear Basic UDI-DI: 506016805AHGBQ Device identifiers: 415010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
AHG Elite Green Basic UDI-DI: 506016805AHGBQ Device identifiers: 435010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
Anti-Human IgG Clear Basic UDI-DI: 506016805AHGBQ Device identifiers: 401010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	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
Anti-Human IgG Green Basic UDI-DI: 506016805AHGBQ Device identifiers: 402010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
Anti-Jka Monoclonal Basic UDI-DI: 506016805KIDD5Y Device identifiers: 775002	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
Anti-Jkb Monoclonal Basic UDI-DI: 506016805KIDD5Y Device identifiers: 776002	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-027/2022 NB# 1434
Monoclonal Rh Control Basic UDI-DI: 506016805RHPE Device identifiers: 640010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-025/2022 1434-IVDD-026/2022 NB# 1434
Monoclonal D Negative Control Basic UDI-DI: 506016805RHPE Device identifiers: 650010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-025/2022 1434-IVDD-026/2022 NB# 1434
Anti-A Monoclonal Basic UDI-DI: 506016805ABOBN Device identifiers: 600010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-B Monoclonal Basic UDI-DI: 506016805ABOBN Device identifiers: 610010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434
Anti-A,B Monoclonal Basic UDI-DI: 506016805ABOBN Device identifiers: 620010	Class D incl. ST/NPT	N/A	Certification as follows: 1434-IVDD-074/2022 1434-IVDD-075/2022 NB# 1434

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-02-28	713333265; PO 14941; PO 14942; PO 14943; PO 14944; PO 14945; 75959970	Initial issue