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

Bosch Healthcare Solutions GmbH  
Stuttgarter Strasse 130  
71332 Waiblingen  
Germany

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
94600	713226555, 713369741	medical_devices@tuvsud.com	-	2025-03-18	1 of 6

**TÜV SÜD Product Service GmbH  
Confirmation Letter  
CLI 094600 0013 Rev. 00**

**Reference: 713226555, 713369741**

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: **DE-MF-000024061**

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.

**Registered Office: Munich**  
Trade Register Munich HRB 85742  
UniCredit Bank GmbH · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
VAT ID No. DE129484267  
Information pursuant to § 2 [1] DL-InfoV  
(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
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If devices covered by certificates issued under 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=cert:CLI\\_094600\\_0013](http://www.tuvsud.com/ps-cert?q=cert:CLI_094600_0013)

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2025-03-18

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to read 'K. Gramlich'.

Dr. Kristina Gramlich  
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to read 'Matthias Mumme'.

Matthias Mumme (18. März 2025 16:00 GMT+1)

Matthias Mumme  
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
<b>Device 1</b>  <b>Vivalytic STI</b>  <b>Basic UDI-DI</b> <b>4059233STI000R5</b>	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 094600 0006 Rev. 01; NB#0123

**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
N/A	N/A	N/A	N/A

**Confirmation Letter Version History**

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2025-03-18	713226555, 713369741	Initial issue



## Attachment

Additional Information for the devices listed in the table(s) above:

Device name or Basic UDI-DI (under IVDR application)	Ref.No.
Vivalytic STI	F09G300078 F09G301142

2025-03-18

TÜV SÜD Product Service GmbH  
Medical and Health Services

A handwritten signature in black ink, appearing to read 'K. Gramlich'. The signature is written in a cursive, flowing style.

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Dr. Kristina Gramlich  
Conformity Assessment Responsible (CARE)