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

Bosch Healthcare Solutions GmbH
Stuttgarter Strasse 130
71332 Waiblingen

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
094600	713333109_CLI	medical_devices@tuvsud.com	-	2025-02-05	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 094600 0012 Rev. 00

Reference: **713333109, 713333109_AR**
713226555-IVDR, 713226555-AR

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.

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 July 2024, without having been withdrawn, this letter also confirms that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 0012

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2025-02-05

TÜV SÜD Product Service GmbH
Medical and Health Services

K. Gramlich

Dr. Kristina Gramlich
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias Mumme
Matthias Mumme (6. Februar 2025 09:08 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
Device 1 **Vivatmo me Western Europe** **Vivatmo me Eastern Europe** **Vivatmo me Asia**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 094600 0006 Rev. 01; NB#0123
Device 2 **Vivatmo me Oxycap**	Class C incl. ST/NPT/CDx	N/A	Certification as follows: V1 094600 0006 Rev. 01; NB#0123
Device 3 **Vivatmo me Level 0**	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
2025-02-05	713333109_CLI	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.**
Vivatmo me Western Europe Vivatmo me Eastern Europe Vivatmo me Asia	F09G100149 F09G100525 F09G100526
Vivatmo me Oxycap	F09G100124
Vivatmo me Level 0	F09G100174

2025-02-05

TÜV SÜD Product Service GmbH
Medical and Health Services

Dr. Kristina Gramlich
Conformity Assessment Responsible (CARE)