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

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Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
89675	713338268; 713338276	medical_devices@tuvsud.com	-	2024-08-08	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 089675 0011 Rev. 00

Reference: 713338268 | 713338276

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: CN-MF-000015566

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)
Patrick van Welij

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Certification Body for Medical Products
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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_089675_0011

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-08

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

[Michael Mauermeir \(Aug 8, 2024 09:59 GMT+2\)](#)

Ms. Rong Li
Conformity Assessment Responsible (CARE)

Mr. 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
Coronavirus (2019-nCoV)-Antigentest- Basic UDI-DI: 697029753318LL	Class D incl. ST/NPT	N/A	Certification as follows: V9 089675 0006 Rev. 01 (VCP 089675 0007 Rev.00) (VCP 089675 0010 Rev.00) 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
Not applicable	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
2024-08-08	713338268; 713338276	Initial issue



Attachment

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

Device name or Basic UDI-DI (under IVDR application)	Device reference under IVDR	Device reference under IVDD
Coronavirus (2019-nCoV) -Antigentest-	HGCG31800101 (1 test/kit) HGCG31800201 (1 test/pack) HGCG31800202 (2 tests/pack)	HGCG134S0101 (1 test/kit) HGCG134S0101 (1 test/pack) HGCG134S0102 (2 tests/pack)
Basic UDI-DI: 697029753318LL	HGCG31800105 (5 tests/kit) HGCG31800107 (7 tests/kit) HGCG31800120 (20 tests/kit) HGCG31800140 (40 tests/kit)	HGCG134S0105 (5 tests/kit) HGCG134S0107 (7 tests/kit) HGCG134S0120 (20 tests/kit) HGCG134S0140 (40 tests/kit)

2024-08-08

TÜV SÜD Product Service GmbH
Medical and Health Services

Ms. Rong Li
Conformity Assessment Responsible (CARE)