Manufacturer´s Declaration

To whom it may concern

VIDIA spol. s r.o. as manufacturer declare following:

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate)
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	VIDIA spol.s r.o.
Manufacturer address and contact details	Nad Safinou II 365, 252 50 Vestec info@vidia.cz orders@vidia.cz
Single Registration Number (SRN)	CZ-MF-000036964

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☐ 26 May 2026 for class C devices

☐ 27 May 2027 for class B and class A (sterile) devices

- **Directive Certificate EC Certificate**

  Full Quality Assurance System No. 20 0415 QS/NB issued by ITC Zlín, Notified Body 1023 (INSTITUE FOR TESTING AND CERIFICATION, Inc., Zlín, Czech Republic) as listed above or in the attached schedule

  - Directive Certificate covering the devices listed in the attached schedule was issued after 25 May 2017, was valid on 26 May 2025 and has not been withdrawn afterwards.

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has been lodged by us to a notified body before 26 May 2025 for the device(s) listed in the attached schedule. And signed written agreement(s) will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  QMS in accordance with Article 10(8) IVDR is in place.

- **Device(s) listed in the attached schedule**

  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

In Vestec, 05.June 2025

Marieta Pribišová,
Quality Manager

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	REF	Classification	Directive Certificate number to which this declaration is issued	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged	End date of extended validity / transition period
ELISA-VIDITEST anti-CMV IgG	OD-176	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG	ODZ-176	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG a avidita IgG	OD-177	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG and IgG avidity	ODZ-177	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG a avidita IgG	OD-105	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG (CSF)	OD-102	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG (CSF)	OD-102/5ST	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG (CSF)	OD-103	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG (CSF)	ODZ-102	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgG (CSF)	ODZ-102/5ST	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgA	OD-164	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgA	ODZ-164	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-CMV IgM	OD-402	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027

Identification of the device(s)	REF	Classification	Directive Certificate number to which this declaration is issued	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged	End date of extended validity / transition period
ELISA-VIDITEST anti-CMV IgM	ODZ-402	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgG	K-130-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgG	KZ-130-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgG avidita	K-133-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgG avidity	KZ-133-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgM	K-131-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgM	KZ-131-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgA	K-132-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-CMV IgA	KZ-132-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgG	OD-457	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgG	ODZ-457	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgM	OD-458	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgM	ODZ-458	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgA	OD-459	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia pneumoniae IgA	ODZ-459	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027

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MONO-VIDITEST anti-Chlamydia pneumoniae IgG	K-230-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia pneumoniae IgG	KZ-230-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia pneumoniae IgM	K-231-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia pneumoniae IgM	KZ-231-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia pneumoniae IgA	K-232-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia pneumoniae IgA	KZ-232-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia trachomatis IgG	OD-464	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia trachomatis IgG	ODZ-464	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia trachomatis IgA	OD-465	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Chlamydia trachomatis IgA	ODZ-465	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia trachomatis IgG	K-220-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia trachomatis IgG	KZ-220-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia trachomatis IgA	K-222-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Chlamydia trachomatis IgA	KZ-222-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgG	OD-481	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027

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ELISA-VIDITEST anti-Toxoplasma gondii IgG	ODZ-481	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgG a avidita IgG	OD-482	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgG and IgG avidity	ODZ-482	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgM	OD-483	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgM	ODZ-483	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgA	OD-480	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
ELISA-VIDITEST anti-Toxoplasma gondii IgA	ODZ-480	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgG	K-210-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgG	KZ-210-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgG avidita	K-213-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgG avidity	KZ-213-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgM	K-211-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgM	KZ-211-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgA	K-212-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027
MONO-VIDITEST anti-Toxoplasma gondii IgA	KZ-212-12	C	EC Certificate-Full QMS No. 20 0415 QS/NB	ITC Zlin, NB1023	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2027

Identification of the device(s)	REF	Classification	Directive Certificate number to which this declaration is issued	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged	End date of extended validity / transition period
ELISA-VIDITEST anti-VCA EBV IgG	OD-065	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG	OD-265	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG	ODZ-265	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG and avidity IgG	OD-095	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG and IgG avidity	OD-175	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG and avidity IgG	ODZ-175	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG (CSF)	OD-084	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG (CSF)	OD-084/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG (CSF)	OD-091	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG (CSF)	OD-091O	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgG (CSF)	ODZ-084	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgM	OD-287	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgM	ODZ-287	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgM	ODZ-005	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VCA EBV IgA	OD-096	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

Identification of the device(s)	REF	Classification	Directive Certificate number to which this declaration is issued	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged	End date of extended validity / transition period
ELISA-VIDITEST anti-VCA EBV IgA	ODZ-096	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgG	K-100-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgG	KZ-100-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgG and avidity IgG	K-103-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgG and avidity IgG	KZ-103-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgM	K-101-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgM	KZ-101-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgA	K-102-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VCA EBV IgA	KZ-102-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgG	OD-062	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgG	OD-277	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgG	OD-412	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgG	ODZ-001	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgG	ODZ-412	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EBNA-1 EBV IgM	OD-037	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

Identification of the device(s)	REF	Classification	Directive Certificate number to which this declaration is issued	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the IVDR application was lodged	End date of extended validity / transition period
ELISA-VIDITEST anti-EBNA-1 EBV IgM	ODZ-002	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgG	OD-097	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgG	OD-099	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgG	ODZ-006	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgM	OD-098	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgM	ODZ-007	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgA	OD-254	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-EA (D) EBV IgA	ODZ-254	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EBNA-1 EBV IgG	K-110-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EBNA-1 EBV IgG	KZ-110-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EBNA-1 EBV IgM	K-111-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EBNA-1 EBV IgM	KZ-111-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EA (D) EBV IgG	K-120-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EA EBV IgG	KZ-120-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-EA (D) EBV IgM	K-121-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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MONO-VIDITEST anti-EA EBV IgM	KZ-121-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG	OD-235	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG	OD-235/A	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG	ODZ-235	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG (CSF)	OD-344	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG (CSF)	OD-344/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgG (CSF)	ODZ-344	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgM	OD-345	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgM	OD-345/A	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HHV-6 IgM	ODZ-345	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HHV-6 IgG	K-160-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HHV-6 IgG	KZ-160-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HHV-6 IgM	K-161-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HHV-6 IgM	KZ-161-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-JCV IgG	OD-450	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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ELISA-VIDITEST anti-JCV IgG	ODZ-450	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-BKV IgG	OD-405	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-BKV IgG	ODZ-405	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgG	OD-369	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgG	ODZ-369	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgG (CSF)	OD-169	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgG (CSF)	ODZ-169	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgM	OD-234	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgM	ODZ-234	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgA	OD-283	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-HSV 1+2 IgA	ODZ-283	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HSV 1+2 IgG	K-140-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HSV 1+2 IgG	KZ-140-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HSV 1+2 IgM	K-141-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HSV 1+2 IgM	KZ-141-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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MONO-VIDITEST anti-HSV 1+2 IgA	K-142-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-HSV 1+2 IgA	KZ-142-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF)	OD-087	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF)	OD-087/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF)	ODZ-087/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF)	ODZ-168	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF) and avidity IgG	OD-233	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgG (CSF) and avidity IgG	ODZ-233	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgM	OD-197	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgM	ODZ-197	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgA	OD-284	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-VZV IgA	ODZ-284	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgG avidity	K-150-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgG avidity	KZ-150-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgG avidity	K-153-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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MONO-VIDITEST anti-VZV IgG avidity	KZ-153-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgM	K-151-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgM	KZ-151-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgA	K-152-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-VZV IgA	KZ-152-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgG + VIsE (CSF)	OD-398	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgG + VIsE (CSF)	ODZ-398	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgG + VIsE (CSF)	OD-398/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgG + VIsE (CSF)	ODZ-398/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgM (CSF)	OD-399	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgM (CSF)	ODZ-399	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgM (CSF)	(OD-399/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Borelia recombinant IgM (CSF)	ODZ-399/5ST	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Borrelia sp. IgG + VIsE	K-300-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Borrelia sp. IgG + VIsE	KZ-300-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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MONO-VIDITEST anti-Borrelia sp. IgM	K-301-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Borrelia sp. IgM	KZ-301-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST CXCL13	OD-510	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST CXCL13	ODZ-510	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST CXCL13	K-634-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST CXCL13	KZ-634-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgG (CSF)	OD-192	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgG (CSF)	ODZ-192	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgG and IgG avidity	OD-170	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgG and IgG avidity	ODZ-170	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgM	OD-194	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-TBEV IgM	ODZ-194	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-TBEV IgG	K-310-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-TBEV IgG	KZ-310-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-TBEV IgG avidity	K-313-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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MONO-VIDITEST anti-TBEV IgG avidity	KZ-313-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-TBEV IgM	K-311-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-TBEV IgM	KZ-311-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgG	OD-137	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgG	ODZ-010	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgM	OD-138	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgM	ODZ-011	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgA	OD-139	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Mycoplasma pneumoniae IgA	ODZ-012	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgG	K-400-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgG	KZ-400-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgM	K-401-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgM	KZ-401-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgA	K-402-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Mycoplasma pneumoniae IgA	KZ-402-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028

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ELISA-VIDITEST anti-Pseudomonas aeruginosa IgG	OD-526	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST anti-Pseudomonas aeruginosa IgG	ODZ-526	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Pseudomonas aeruginosa IgG	K-430-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
MONO-VIDITEST anti-Pseudomonas aeruginosa IgG	KZ-430-12	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
ELISA-VIDITEST complement factor H	OD-166	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST complement factor H	ODZ-166	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST Interferon γ	OD-326	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST Interferon γ	ODZ-326	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgA	OD-514	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgA	ODZ-514	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgG	OD-512	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgG	ODZ-512	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgM	OD-513	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
ELISA-VIDITEST anti-Aspergillus fumigatus IgM	ODZ-513	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
MONO -VIDITEST anti-Aspergillus fumigatus IgA	K-702-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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MONO -VIDITEST anti-Aspergillus fumigatus IgA	KZ-702-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
MONO-VIDITEST anti-Aspergillus fumigatus IgG	K-700-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
MONO-VIDITEST anti-Aspergillus fumigatus IgG	KZ-700-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
MONO-VIDITEST anti-Aspergillus fumigatus IgM	K-701-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
MONO-VIDITEST anti-Aspergillus fumigatus IgM	KZ-701-12	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
				–		
RAPID-VIDITEST Adenovirus	OD-285	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Adenovirus	ODZ-285	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Astrovirus	OD-186	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Astrovirus	ODZ-186	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Clostridium dificille Ag (GDH)	OD-330	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Clostridium dificille Ag (GDH)	ODZ-330	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST C. dificille GDH + Toxin A+B	OD-449	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST C. dificille GDH + Toxin A+B	ODZ-449	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Campylobacter	OD-160	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RAPID-VIDITEST Campylobacter	ODZ-160	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Campylobacter	OD-161	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Crypto	OD-278	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Crypto	ODZ-278	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Crypto-Giardia	OD-039	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Crypto-Giardia	ODZ-055	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Crypto-Giardia	ODZ-255	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST E.coli O157:H7	OD-040	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
RAPID-VIDITEST E.coli O157:H7	ODZ-028	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
RAPID-VIDITEST Entamoeba	OD-223	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Entamoeba	ODZ-223	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Enterovirus	OD-187	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Enterovirus	ODZ-187	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Giardia	OD-028	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Giardia	OD-038	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RAPID-VIDITEST Giardia	ODZ-016	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Giardia	ODZ-257	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-023	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-128	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-129	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-130	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-131	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-142	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-143	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-145	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-146	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-147	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-291	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	OD-148	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST H.pylori	ODZ-128	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RAPID-VIDITEST H.pylori	ODZ-129	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rotavirus	OD-246	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rotavirus	ODZ-246	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-122	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-123	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-124	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-125	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-126	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-127	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-149	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	OD-150	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	ODZ-122	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno	ODZ-123	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno-Noro	OD-422	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Rota-Adeno-Noro	ODZ-422	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RAPID-VIDITEST Norovirus	OD-346	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Norovirus	ODZ-346	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Salmonela	OD-174	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Salmonela	ODZ-174	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Yersinia entrocolitica 0:3	OD-258	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Yersinia entrocolitica 0:3	ODZ-258	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Adenovirus Resp.	OD-051	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Adenovirus Resp.	OD-052	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Adenovirus Resp.	ODZ-052	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV	OD-055	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV	OD-056	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV	ODZ-021	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV	ODZ-065	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV + Adeno Resp.	OD-059	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV + Adeno Resp.	OD-060	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RAPID-VIDITEST RSV + Adeno Resp.	OD-061	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV + Adeno Resp.	OD-064	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV + Adeno Resp.	ODZ-062	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST RSV + Adeno Resp.	ODZ-023	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	OD-133	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	OD-134	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	OD-135	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	OD-136	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	ODZ-134	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Influenza A+B	ODZ-026	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Strep A	OD-068	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Strep A	ODZ-068	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Streptococcus pneumoniae	OD-370	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Streptococcus pneumoniae	ODZ-370	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Adenovirus Positive Control	ODZ-202	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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Astrovirus Positive Control	ODZ-204	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
C.difficile GDH Positive Control	ODZ-334	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
C. difficile GDH-Toxin A+B Positive control	ODZ-499	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Campylobacter Positive control	ODZ-208	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Crypto Positive control	ODZ-205	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Giardia Positive control	ODZ-206	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
E. coli Positive Control	ODZ-207	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Entamoeba Positive Control	ODZ-226	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Enterovirus Positive Control	ODZ-203	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Helicobacter Pylori Positive Control	ODZ-211	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Rotavirus Positive Control	ODZ-201	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Rota-Adeno-Noro Positive Control	ODZ-498	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Salmonella Positive Control	ODZ-209	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Yersinia O:3 Positive Control	ODZ-518	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Adenovirus Resp. Positive Control	ODZ-214	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029

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RSV Positive Control	ODZ-213	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Influenza A+B Positive Control	ODZ-216	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
Strep A Positive Control	ODZ-212	B	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2029
RAPID-VIDITEST Calprotectin	OD-248	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
RAPID-VIDITEST Calprotectin	ODZ-248	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
Calprotectin Positive Control	ODZ-288	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
RAPID-VIDITEST Lactoferrin	OD-085	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
RAPID-VIDITEST Lactoferrin	ODZ-085	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028
Lactoferrin Positive Control	ODZ-198	C	The involvement of a notified body is not required according to the IVDD	–	TÜV Rheinland LGA Products GmbH, NB0197	31 December 2028