



PRIMA Lab SA
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CHE- 301.179.156
ISO 13485:2016

Manufacturer's Declaration

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 *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Prima Lab SA
Manufacturer address and contact details	Via Antonio Monti 7, CH-6828 Balerna
Single Registration Number (SRN) (if available)	CH-MF-000034473

Authorised Representative name (if applicable)	QbD RepS BV.
Authorised Representative address and contact details	Groenenborgerlaan 16 2610 Wilrijk Belgium
Single Registration Number (SRN) (if available)	BE-AR-000000040

Notified body name (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
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Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
End date of extended validity/transition period	<input checked="" type="checkbox"/> See attached schedule

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:

Choose applicable statement:

- 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



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Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

- 26 September 2025 for class D devices
- 26 September 2026 for class C devices
- 27 September 2027 for class B and class A (sterile) devices

We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

Original expiry date *before 9 July 2024*:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or
- Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or
- Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:

- 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 no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.
- We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

Original expiry date *after 9 July 2024*:

Choose one applicable statement:

- 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 no later than 26 May 2025 for the device(s)



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listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.

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

Notified body has issued the attached certificate for the IVDR-compliant QMS.

➤ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- 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:

PRIMA LAB SA
Firmato da:

537D3C1D911F4F0...

Alberto Gianni

(CEO)

PRIMA LAB SA

Date: 15th December 2025



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Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	End date of extended validity / transition period	Substitute Device(s) (if applicable)	Directive Certificate number to which this declaration is issued (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the IVDR application was lodged/contract signed (if applicable)
MENOPAUSE FSH TEST REF. 820011-x	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Berkeleyhealth Menopause FSH (REF. 890011-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
VagivitalMenopause FSH-Test REF.821011-x	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Menopause FSH Gef+ Medica (REF. 827011-2)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Klimakterietest REF. V8002-001	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Menopause FSH Test REF. 90310-2	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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Estromineral Test Menopausa (Ref. 822011-2)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
STREP A TEST (REF.800060-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
PROFAR STREP A TEST (REF.801060-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Strep A (REF 890060-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Self test Streptococco A, diagnosti.care (REF. 850060-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Newfoundland Strep A Self-Test (REF.880060-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
GetTested STREP A Test (REF.830060-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRST PRAEDICT SELF TEST RILEVAZIONE STREPTOCOCCO (REF.826060-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Streptococco A Gef+ Medica (REF.807060-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Autotest Strep A (Ref. STREPTTEST)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
TEST STREPTOCOCCO A (REF. MM-STREP-A)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
TEST A1 (ref.804060-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test för Halsfluss - Test for halsbetennelse - Test for Halsbetændelse Strep A (REF. V8004-001)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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STREP A SELF (REF. STREPTOFERR)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Dr Max Strep A Test (REF: 8880060-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
C-Reactive Protein test (REF. 800034-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
CRP Test (REF. 880034-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth C-Reactive Protein (REF.890034-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
GetTested CRP Test (REF.830034-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
CRP-Test (REF.803434-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
H&W tulehduspikatesti CRP (REF. HW-800034-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Body Inflammation Self-test (REF. SI-CRP)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
TEST CRP - na bialko C-reaktywne (REF. 804034-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
ZuhauseTEST CRP (Ref. 730000)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Vitamin D Test (REF.100066-x)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Autodiagnostico Vitamina D (REF.101166-x)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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berkeleyhealth Vitamin D (REF.190066-x)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Self Care Test rapid Vitamina D (REF. SC026)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRST PRAEDICT SELF TEST MISURAZIONE VITAMINA D (REF.826066-1)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Kruidvat Vitamine D zelftest (REF. 101266-1)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Vitamina D Gef+ Medica (REF.107066-1)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Autotest Vitamina D (REF.VITDTEST)	31 Dec 2027	YES	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Vaginal pH Test (REF.100013-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Vaginal pH (REF. 190013-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Vaginaler pH-Wert Selbsttest (REF. 6107)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Newfoundland Vaginal Infection Test (REF. 180013-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Vaginal pH Test (REF.GS01.2075)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Celiac Test (REF.100077-x)	31 Dec 2027	CELIAC DISEASE SCREENING TEST(764016 486CE2H867)	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
MyTest-Celiachia (REF.300077)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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Test Autodiagnostico Celiachia (REF.101177-x)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Berkeleyhealth Celiac (REF.190077-x)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Self test Celiachia, diagnosti.care (REF.150077-x)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Wellgio KELIAKIAN PIKATESTI (REF.79640090)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
GetTested CELIAC TEST (REF.130077-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
COELIAC SELF TEST (REF. 110077-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
NEWFOUNDLAND COELIAC TEST (REF.180077-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
ALLBRIEFS TEST CELIACO (REF. 008709.7)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Celiachia Gef+ Medica (REF. 107077-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
TEST CELIACHIA (REF. MM-CEL)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
AYDMED COELIAC TEST (REF.AM-CT-01-UK)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
ValMed Celiac Test (REF.131277-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
SoFarma Più Test Glutine (REF.SF004)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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Test Glutine (REF. 191977-1)	31 Dec 2027	CELIAC DISEASE SCREENING TEST	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 Self-Test (REF. 800062-1)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 Self-Test (REF. 800062-1H)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 Self-Test (REF. 800062-1PB)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Berkeleyhealth HIV (REF.890062-1)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Self test HIV 1/2, diagnosti.care® (REF.850062-1)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
SoFarmaPiù Test HIV 1/2 (REF.SF014)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Veneris Test rapid HIV 1& 2 (REF.VNS20)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 SELF-TEST (REF.800062-1CS)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 SELF-TEST (REF.800062-1SP-CU)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 SELF-TEST (REF.800062-1-SP-DS)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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Test Hiv 1/2 Gef+ Medica (REF.807062-1)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 SELF-TEST (REF.800062-1IFSP)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Horny Hive HIV Selbsttest (REF.801562-1)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Aydmed HIV Test (REF.AM-HT-01-EU)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Autotest HIV1/2 (REF.HIVTEST)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 Self-Test (REF. 800062-1-RE-KU)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1 & 2 Self-Test (REF. 809062-1ENS)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 Self-Test (REF. 800062-1-SP-MP)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIV 1/2 SELF-TEST (REF. DGX-PRM-HIV-1T)	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
<i>HIV Test (REF. C-HIV)</i>	31 Dec 2027	N/A	D1408400051 and D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Helicobacter Pylori Antigen Test (REF.800016-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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TEST AUTODIAGNOSTICO HELICOBACTER PYLORI (REF. 801016)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Helicobacter pylori antigen (REF.890016)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRST PRAEDICT SELF TEST RILEVAZIONE HELICOBACTER PYLORI (REF.826016-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Autotest Helicobacter pylori (REF.16165)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Helicobacter pylori Gef+ Medica (REF. 807016-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Iron Fer Test (REF. 800025-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Autodiagnostico Ferro (ref. 801025-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Iron FER (ref. 890025-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRST PRAEDICT SELF TEST MISURAZIONE FERRO (ref 826025-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Ferritina Gef+ Medica (ref. 807025-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Ovulation LH Test (REF.820050-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test di Ovulazione Securtest® (REF. 821050)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Safe&Easy Ovulationstest (REF. 823150)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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berkeleyhealth Ovulation LH (REF. 890050-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Ovulazione LH Gef+ Medica (REF.827050-5)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Kidneys Albumin Test (REF.820027-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Kidney Albumin (REF.890027-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
<i>Kidneys Albumin test (REF. C-ALB)</i>	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Allergy IgE Test (REF. 800018-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Allergy IgE (REF. 890018-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
<i>Allergy IgE test (REF. C-IgE)</i>	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Helicobacter pylori Test (REF.800017-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Helicobacter pylori (REF.890017-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Dr Max Helicobacter pylori Test (REF. 888017-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
SPERM TEST (REF. 100082-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Sperm count (REF. 190082-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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Spermienanzahl Selbsttest (REF. 6106)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
AMNIOCHECK (REF. 100088-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
AMNIOS (REF. 600088)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Barza AmnioTest (REF. 710088)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyheath Amniotic Fluid (REF.190088-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
One+Step Amniocheck (REF. 500088-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
ZuhauseTEST Fructwasser (REF.740000)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Urinary Tract Infections Test (REF.100058-x)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
MyTest Infection Urinarie (REF. 300058)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Vidi Pharma Selvttest Urinveisinfeksjon (REF. 102058-x)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Berkeleyhealth Urinary Tract Infection (REF. 190058-x)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
VagiVital Urinary Tract Infection self test (REF.110058-x)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Blasenentzündung Selbsttest (REF.6124)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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PRODECOPHARMA - URINARY TRACT INFECTION TEST (REF. GS01.2070)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Veneris Test rapid pentru infectii urinare (REF. VNS01)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Kruidvat Urineweginfectie zelftest (REF. 101258-3)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Infezioni Tratto Urinario Gef+ Medica (REF.107058-3)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test de infecciones urinarias Nux (REF. 160058-3)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Urinary Tract Infections Test (REF. 130058-x)	31 Dec 2027	Yes	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Prostate PSA Test (REF.800080-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Profar Test PSA (REF. 801080)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Prostate PSA (REF.890080-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Prostate Health Test, Newfoundland® (REF.880080-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
GetTested PROSTATE PSA TEST (REF. 830080-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Kruidvat Prostaat zelftest (REF. 801280-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
TEST PROSTATA (REF.MM-PSA)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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PROSTATE HEALTH TEST (REF.810080-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
PROSTATE PSA TEST (DGX-PRM-PSA-1T)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Zuhause TEST PSA (Ref.720000)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Bowel FOB Test (REF.800040-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Profar Test Colon Retto (REF.801040)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Bowel FOB (REF. 890040-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Bowel FOB Home Test Kit (REF. 880040-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRST PRAEDICT SELF TEST RILEVAZIONE SANGUE OCCULTO NELLE FECI (REF. 826040-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Early Pregnancy Test (REF.820010-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
berkeleyhealth Early Pregnancy (REF. 890010-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
activeMED Schwangerschaftstest (REF. 730483)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
GRAVIDITETSTEST (ref. V8001-001)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FarmaSi-test di gravidanza precoce, Test De Grossesse Précoce, Schwangerschaftsfruchttest - Early Pregnancy Test (ref 825410-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

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axaclear early (REF. 80002)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
axaclear early (ref. 80003)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Test Gravidanza precoce Gef+ Medica (ref. 827010-2)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
FIRSTPRAEDICT CARE FOR YOU (REF.826010-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
SANAVITA Test di Gravidanza (ref. 823010-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
Höga hCG-Control Schwangerschaftstest (ref. 06616995)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
COOP Early Pregnancy Test (REF. 825710-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
PiùME MEDICAL Early Pregnancy Test (REF. 845010-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
ESSERE BENESSERE Early Pregnancy Test (ref. 825110-x)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
MEDICAZIONE Test di Gravidanza Precoce/Early Pregnancy (REF.825310-1)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
HIGHMED Technology Test di Gravidanza precoce(ref.825210)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH
QUALITY MED test di Gravidanza Precoce (ref. 824910)	31 Dec 2027	N/A	D1408400052	26/05/2025	0483 mdc medical device certification GmbH	0483 mdc medical device certification GmbH

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

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