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Nur zur elektronischen Verbreitung

# EU Quality Management System Certificate

We hereby certify the company

**PRIMA Lab SA**
**Via Antonio Monti 7**
**6828 Balerna**
**Switzerland**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/746 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

## Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/746.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

| | | | |
|---|---|---|---|
| Valid from | 2025-09-11 | Registration No. | D1408400102 |
| Valid until | 2028-10-25 | Report No. | P24-01364-313668 |

Stuttgart, 2025-09-11

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-098

## EU Authorized Representative:

QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium
BE-AR-000000040

## Devices:

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Immunoassays intended to be used for screening / confirmation / of specific disorders / impairment

Risk class: C self-testing
W0102 IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays

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Immunoassays intended to be used for detection of pregnancy or fertility testing

Risk class: B self-testing
IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing

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## Notes:

For class A devices placed on the market in sterile condition the involvement of mdc is limited to the assessment of the aspects of manufacture concerned with securing and maintaining sterile conditions.

For devices for self-testing and near-patient testing the involvement of mdc additionally refers to the assessment of aspects according to Annex IX, Section 5.1.

For the placing on the market of class D devices an EU technical documentation assessment certificate is also required.

## The certificate is based on the previous certificate

D1408400089 (2024-09-24)

with the following changes to D1408400089:
Extension to new product group – Class B self-test IVR 0607