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Nur zur elektronischen Verbreitung

EU Technical Documentation Assessment Certificate

We hereby certify that the company

PRIMA Lab SA
Viale Serfontana 10
6834 Morbio Inferiore
Switzerland

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/746, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

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

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	2026-04-29	Registration No.	D1408400109
Valid until	2031-04-28	Report No.	P24-01554-317528

Stuttgart, 2026-04-29

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:

HIV 1/2 TEST (REF: HV2H88000KIT01EN, HV2H88000KIT01IT)

Intended purpose: Rapid immunochromatographic manual self-test for the qualitative detection of antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) in human capillary blood to assist the identification of HIV infection.

Risk class: D self-testing
Basic UDI-DI: 764016486HV2H8BM

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/746 on in vitro diagnostic medical devices is also required.