

Certificate

mdc medical device certification GmbH
certifies that



PRIMA Lab SA
Via Antonio Monti 7
6828 Balerna
Switzerland

with the locations listed in the attachment

for the scope

**design and development, manufacturing, distribution and service of
immunochemographic, colorimetric and dry-chemistry rapid tests as well as
digital measuring systems for professional use and self-testing;**

**contract design, development and manufacturing of IVD in the field of
immunochemographic, colorimetric and dry-chemistry rapid tests**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-12-08
Valid until	2026-12-07
Registration no.	D1408400074
Report no.	P23-01111-276412
Stuttgart	2023-12-07

Head of Certification Body



Attachment of the certificate

No. D1408400074

date 2023-12-07

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Location	Scope
PRIMA Lab SA Via Antonio Monti 7 6828 Balerna Switzerland	design and development, manufacturing, distribution and service of immunochromatographic, colorimetric and dry-chemistry rapid tests as well as digital measuring systems for professional use and self-testing; contract design, development and manufacturing of IVD in the field of immunochromatographic, colorimetric and dry-chemistry rapid tests
PRIMA Lab SA Via Antonio Monti 9 6828 Balerna Switzerland	final kit assembly and storage of products; contract manufacturing of IVD in the field of immunochromatographic, colorimetric and dry-chemistry rapid tests





Head of Certification Body