

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 services of
in-vitro diagnostic devices for professional use and self-testing**

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:2016 - ISO 13485:2016

Valid from	2023-02-08
Valid until	2023-12-07
Registration no.	D1408400057
Report no.	P22-01612-260188
Stuttgart	2023-02-08

Head of Certification Body



Attachment of the certificate

No. D1408400057

date 2023-02-08

Page 1 of 1

Location	Scope
PRIMA Lab SA Via Antonio Monti 7, 6828 Balerna	design and development, manufacturing, distribution and services of in-vitro diagnostic devices for professional use and self-testing
PRIMA Lab SA Via Antonio Monti 9, 6828 Balerna	final kit assembly and storage of products





Head of Certification Body