

Certificate

mdc medical device certification GmbH
certifies that



**Via Antonio Monti 7
6828 Balerna
Switzerland**

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	2018-09-15
Valid until	2021-09-14
Registration no.	D1408400015
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Stuttgart	2018-08-20

Head of Certification Body

