

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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2016-01-19
Valid until	2019-01-18
Registration no.	D1408400002
Report no.	P15-01213-52917
Stuttgart	2016-01-19

Head of Certification Body

