

# Certificate

We hereby certify the company

**Effectum Medical AG**  
**Kirchgasse 11**  
**4600 Olten**  
**Switzerland**

the introduction and application of a

## **Quality management system according to EN ISO 13485**

in the scope

Design and development, manufacture and distribution of non-sterile, single use breath specimen collection in-vitro diagnostic devices

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016  
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-06-28  
Valid until 2028-06-27

Registration No. D1506600003  
Report No. P25-00379-328463

Stuttgart, 2025-06-03

  
Certification Body