

Certificate

We hereby certify the company

myPOLS Biotec GmbH
Byk-Gulden-Str. 2 // 10
78467 Konstanz
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

development, manufacture and distribution of reagents with polymerase-based systems
for use in in-vitro diagnostics

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 2025-04-17
Valid until 2028-04-16

Registration No. D1449400005
Report No. P25-00065-322085

Stuttgart, 2025-04-16



Certification Body

