

Certificate

mdc medical device certification GmbH
certifies that

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

for the scope

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

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:2018 + A11:2021 - ISO 13485:2016

Valid from	2023-03-28
Valid until	2025-04-16
Registration no.	D1449400004
Report no.	P23-00242-259625
Stuttgart	2023-03-28


Head of Certification Body

