

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:2016 - ISO 13485:2016

Valid from	2022-04-17
Valid until	2025-04-16
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Head of Certification Body

