

Certificate

mdc medical device certification GmbH
certifies that

Gold Standard Diagnostics Frankfurt GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

for the scope

**development, manufacturing and distribution of in-vitro diagnostics as well as
installation and service of IVD analyzers for infectious disease diagnostics,
autoimmune diagnostics, tumor diagnostics and for clinical chemistry**

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

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Head of Certification Body

