

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

Valid from	2023-10-24
Valid until	2024-12-03
Registration no.	D1055500021
Report no.	P23-01379-282119
Stuttgart	2023-10-24


Head of Certification Body



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710010**

Certificate Holder: **Gold Standard Diagnostics
Kassel GmbH**
Otto-Hahn-Str. 16
34123 Kassel
Germany

Scope: Design and development, manufacture and distribution of in vitro immuno diagnostic test kits for the determination of food ingredients as well as antibodies against allergens, infectious agents and autoimmune antigens for human and veterinary diagnostic applications

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2023-11-13 until 2026-11-12.
First certification 2017

2023-09-28



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 1701347-1
Certificate Holder	Gold Standard Diagnostics Kassel GmbH Otto-Hahn-Str. 16 34123 Kassel Germany
Scope	Design and development, manufacture and distribution of in vitro immune diagnostic test kits for the determination of antibodies against allergens, infectious agents and autoimmune antigens

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	1133776-40
Effective date	2023-10-31
Expiry date	2026-10-30
Issue date	2023-09-27
Replaces certificate SX 1701347-1 issued 2023-03-29	



Dr. Matthias Fischer
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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Supplement to the Certificate
according to 98/79/EC, Annex IV, excluding 4 and 6
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Manufacturer	Gold Standard Diagnostics Frankfurt GmbH
Certificate	No. D1055500019 Date: 2022-05-03 immunodiagnostics for the determination of antibodies against Toxoplasma gondii, Rubella virus, Cytomegalovirus and Chlamydia (see attachment)
Products concerned	immunodiagnostics for the determination of antibodies against Toxoplasma gondii, Rubella virus, Cytomegalovirus and Chlamydia
Intended change	New company name: Gold Standard Diagnostics Frankfurt GmbH
Review report no.	P23-01379-282121

The intended change is in compliance with the requirements of the Directive 98/79/EC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until:	2025-05-26
Registration no.:	D1055500022
Stuttgart	2023-10-24


Head of Notified Body

