



CERTIFICATE



This is to certify that

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Development, manufacture and distribution of basic chemicals, special chemical products and analytical systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no. 005356 QM15
Valid from 2023-11-24
Valid until 2026-11-23
Date of certification 2023-11-09



DQS GmbH

Christian Gerling
Managing Director

DQS IS A MEMBER OF





Certificate

No. Q5 034909 0117 Rev. 01

Holder of Certificate: **Merck KGaA**

Frankfurter Straße 250
64293 Darmstadt
GERMANY

Facility(ies):

Merck KGaA

Frankfurter Straße 250, 64293 Darmstadt, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution and Sales of In-Vitro Diagnostic Staining Solutions and Kits, Dry Dyes and Universal Reagents for the microscopical examination of bacteriological, hematological, histological and cytological samples.

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 034909 0117 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_034909_0117_Rev_01)

Report No.: 713302894

Valid from: 2023-11-16

Valid until: 2026-11-15

Date, 2023-10-25

Christoph Dicks

Head of Certification/Notified Body



CERTIFICATE



This is to certify that

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains an **Environmental Management System**.

Scope:

Development, production and distribution of pharmaceuticals, chemical products and analytical systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 14001 : 2015

Certificate registration no.	005356 UM15
Valid from	2023-12-17
Valid until	2026-12-16
Date of certification	2023-11-09



Deutsche
Akkreditierungsstelle
D-ZM-16074-01-00

DQS GmbH

Christian Gerling
Managing Director



DQS IS A MEMBER OF





**Annex to certificate
Registration No. 005356 UM15**

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Germany

Location

**005356
Merck KGaA
Frankfurter Straße 250
64293 Darmstadt
Germany**

Including:

**Merck Real Estate GmbH
An affiliate of Merck KGaA, Darmstadt,
Germany**

**Merck Site Management GmbH
An affiliate of Merck KGaA, Darmstadt,
Germany**

**Merck Electronics KGaA
An affiliate of Merck KGaA, Darmstadt,
Germany**

**Merck Life Science KGaA
An affiliate of Merck KGaA, Darmstadt,
Germany**

**Merck Healthcare KGaA
An affiliate of Merck KGaA, Darmstadt,
Germany**

With regional offices at:

**Waldstrasse 3
64331 Weiterstadt
Germany**

**450237
Merck S.A.
An affiliate of Merck KGaA, Darmstadt,
Germany
Estrada dos Bandeirantes, 1099
Rio de Janeiro - RJ
22710-571
Brazil**

Scope

Development, production and distribution of pharmaceuticals, chemical products and analytical systems.



Production and distribution of pharmaceuticals and chemical products.



Certificate

No. Q5 034909 0117 Rev. 01

Holder of Certificate: **Merck KGaA**
Frankfurter Straße 250
64293 Darmstadt
GERMANY

Facility(ies): **Merck KGaA**
Frankfurter Straße 250, 64293 Darmstadt, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution and Sales of In-Vitro Diagnostic Staining Solutions and Kits, Dry Dyes and Universal Reagents for the microscopical examination of bacteriological, hematological, histological and cytological samples.**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

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Report No.: 713302894
Valid from: 2023-11-16
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Date, 2023-10-25

C. Dicks
Christoph Dicks
Head of Certification/Notified Body