

## **CERTIFICATE**



This is to certify that the company



## metabion international AG

Semmelweisstr. 3 82152 Planegg Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

## Scope:

Design, technical/scientific customer support, Process development, manufacturing, analysis, and sales/distribution of nucleic acid molecules, and associated reagents including formulation and packaging thereof for use in molecular nucleic acid based in-vitro diagnostic assays and applications / Distribution of in-vitro diagnostics (IVD).

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

ISO 13485: 2016

Certificate registration no. 455832 MP2016SCC

Certificate unique ID 1000128877

Effective date 2024-01-17

Expiry date 2027-01-16

Frankfurt am Main 2024-01-08





DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director

Marc Goedecke Product Manager







Annex to certificate

Certificate registration No.: 455832 MP2016SCC

Certificate unique ID: 1000128877

Effective date: 2024-01-17

## metabion international AG

Semmelweisstr. 3 82152 Planegg Germany

Location

536522

metabion international AG Semmelweisstr. 3 82152 Planegg Germany Scope

Design, technical/scientific customer support and sales/distribution of nucleic acid molecules, and associated reagents including formulation and packaging thereof for use in molecular nucleic acid based in-vitro diagnostic assays and applications / Distribution of in-vitro diagnostics

**069201 metabion GmbH** Semmelweisstr. 3 82152 Planegg

Germany

Process development, manufacturing, analysis and sales/distribution of nucleic acid molecules and associated reagents including formulation and packaging thereof for use in molecular nucleic acid based in-vitro diagnostic assays and applications.

549096 metabion GmbH Ammerthalstrasse 26 85551 Kirchheim Germany

Process development, manufacturing and analysis of nucleic acid molecules and derivatives including formulation and packaging thereof for use in molecular nucleic acid based in-vitro diagnostic assays and applications.