

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Dermagnostix GmbH
Georges-Köhler-Allee 302
79110 Freiburg
Germany

Holds Certificate Number:

MD 770663

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of real-time PCR based IVD test kits and analysis instrument for molecular diagnosis in dermatology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-11-15

Latest Revision Date: 2024-01-18

Effective Date: 2022-11-15

Expiry Date: 2025-11-14

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Certificate No: **MD 770663**

Location	Registered Activities
Dermagnostix GmbH Georges-Köhler-Allee 103 79110 Freiburg Germany	Design and development of real-time PCR-based IVD test kits and analysis instrument for molecular diagnosis in dermatology.
Dermagnostix GmbH Siemensstraße 4 79108 Freiburg Germany	Distribution of real time PCR based IVD test kits and analysis instrument for molecular diagnosis in dermatology.
Dermagnostix GmbH Georges-Köhler-Allee 302 Freiburg 79110 Germany	Design and development of real time PCR based IVD test kits and analysis instrument for molecular diagnosis in dermatology.
Dermagnostix GmbH Engesserstraße 4a Freiburg 79108 Germany	Design, development, manufacture and distribution of real time PCR based IVD test kits and analysis instrument for molecular diagnosis in dermatology.
Dermagnostix GmbH Georges-Köhler-Allee 078 Freiburg 79110 Germany	Design and development of real-time PCR-based IVD test kits and analysis instrument for molecular diagnosis in dermatology.

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

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