

Certificate of Registration

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

This is to certify that:

Dermagnostix GmbH
Georges-Köhler-Allee 79
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 a real-time PCR based IVD test kit 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: 2022-11-15

Effective Date: 2022-11-15

Expiry Date: 2025-11-14

Page: 1 of 2



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Certificate No: **MD 770663**

| Location | Registered Activities |
|--|---|
| Dermagnostix GmbH Georges-Köhler-Allee 79 79110 Freiburg Germany | Design, development, manufacture and distribution of a real-time PCR based IVD test kit and analysis instrument for molecular diagnosis in dermatology. |
| Dermagnostix GmbH Georges-Köhler-Allee 103 79110 Freiburg Germany | Design and development of a real-time PCR based IVD test kit for molecular diagnosis in dermatology. |
| Dermagnostix GmbH Siemensstraße 4 79108 Freiburg Germany | Distribution of a real-time PCR based IVD test kit and analysis instrument for molecular diagnosis in dermatology. |



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Page: 2 of 2

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

Information and Contact:

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