

Certificate of Registration

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

This is to certify that:

DSM Nutritional Products Limited
Branch Pentapharm
Dornacherstrasse 112
4147 Aesch
Switzerland

Holds Certificate Number:

MD 701618

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

The design, manufacture and distribution of in-vitro diagnostic reagents and test systems for use in haemostasis diagnostics such as coagulation and fibrinolysis applications. The design, contract-manufacturing and distribution of reagents and substances for use in haemostasis diagnostics such as coagulation and fibrinolysis applications.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-06-25

Latest Revision Date: 2021-07-13

Effective Date: 2021-07-13

Expiry Date: 2024-07-12

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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

Information and Contact:

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