

Certificate of Registration

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

This is to certify that:

02-07-2019 abn
COPY

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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-06-25

Latest Revision Date: 2019-06-25

Effective Date: 2019-06-25

Expiry Date: 2022-06-24

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