

Certificate of Registration

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

This is to certify that:

Pentapharm AG
Dornacherstrasse 112
CH-4147 Aesch BL
Switzerland

Holds Certificate Number:

MD 787070

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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-09-07

Latest Revision Date: 2024-06-24

Effective Date: 2024-07-13

Expiry Date: 2027-07-12

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