By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Pentapharm AG
Dornacherstrasse 112
CH-4147 Aesch BL
Switzerland

Facility ID Number: F005048

Holds Certificate No: **MDSAP 787072**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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, production and distribution of reagents and substances 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: 2023-08-09 Effective Date: 2024-07-13 Expiry Date: 2027-07-12

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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