Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4277)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4277
Certification Granted: August 21, 2007
Effective Date: August 28, 2021
Expiry Date: August 27, 2024

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity	Location
Administration, Design, Manufacturing, Distribution	Penumbra, Inc. One Penumbra Place Building 1351 Alameda, CA 94502 USA File No.: MD19.4277
Administration, Design, Manufacturing, Distribution	Penumbra, Inc. One Penumbra Place Building 1321 Alameda, CA 94502 USA File No.: MD19.4277/A
Design	Penumbra, Inc. One Penumbra Place Building 1411 Alameda, CA 94502 USA File No.: MD19.4277/B
Distribution	Penumbra Europe GmbH Am Borsigturm 44 13507 Berlin Germany File No.: MD19.4277/C

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity	Location
Distribution	Penumbra, Inc. 6336 Patterson Pass Rd Suite D Livermore, CA 94550 USA File No.: MD19.4277/D
Manufacturing	Penumbra, Inc. One Penumbra Place Building 1301 Alameda, CA 94502 USA File No.: MD19.4277/E
Distribution	Penumbra, Inc. 6262 Patterson Pass Rd Suite A Livermore, CA 94550 USA File No.: MD19.4277/F
Manufacturing	Penumbra, Inc. One Penumbra Place Building 1401 Alameda, CA 94502 USA File No.: MD19.4277/G

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity	Location
Distribution	Penumbra Neuro Australia Pty Suite 3, Level 5, 1 Oxford St Darlinghurst Sydney NSW Australia File No.: MD19.4277/H
Distribution	Crossmed SpA, Via Giuseppe di Vittorio 2/C 10098 Rivoli Torino Italy File No.: MD19.4277/I
Distribution	Crossmed SpA, Via Primaticcio 184, 2017 Milano Italy File No.: MD19.4277/J
Distribution	Penumbra, Inc. 1070 South 3800 West Suite 500 Salt Lake City, UT 84104 USA File No.: MD19.4277/K

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity	Location
Manufacturing	Penumbra, Inc. 630 Roseville Parkway Roseville, CA 95747 USA File No.: MD19.4277/L

Verified by:
Operations Manager

CERTIFICATE

This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design and Development, Manufacturing, Sales and Final Control of Product Categories Catheters, Stents, Stent Delivery Systems and endovascular Medical Devices for neurosurgical cardiological and peripheral Applications.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	516802 MP2016
Certificate unique ID	170774421
Effective date	2021-06-19
Expiry date	2024-06-18
Frankfurt am Main	2021-04-28

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

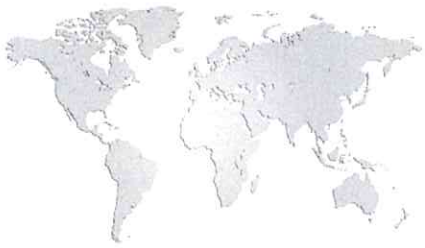
Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

410.90.en Version 1.0

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

InspireMD Ltd.

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

Certified location:

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51168-Z4-00, the decision dated 2019-12-02 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-12-02 to 2024-05-26

Registration No.: 51168-16-05

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-12-02
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 51168-16-05

Valid from 2019-12-02 to 2024-05-26

Revision status of the annex: 0 dated 2019-12-02

Devices/device categories included in the certificate:

Class III:

- MGuard Prime Coronary Stent System – Embolic Protective stent
- CGuard Carotid Embolic Prevention Stent System

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH • DEKRA • Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-12-02
Notified Body ID-number: 0124

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

InspireMD Ltd.

Scope of certification:

Design and development, manufacturing and distribution of Embolic Protective stent systems and Micronet Mesh stent implantation systems for coronary and carotid interventions

Certified location:

4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51168-R1-00.

Certificate registration no.:	51168-14-02	Certificate valid from:	2021-12-21
Validity of previous certificate:	2021-12-20	Certificate valid to:	2024-12-20

DEKRA Certification GmbH Stuttgart Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-12-21

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
242566-2017-AQ-IND-NA-PS Rev. 3.0	**PRJC-517914-2015-MSL-IND**	**17 July 2008**	**17 July 2024**

This is to certify that the management system of:

Meril Life Sciences Private Limited

Muktanand Marg, Chala, Vapi - 396191
Gujarat, India

Complies with the requirements of:
ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:
Design and Development, Manufacture, Distribution, Storage, Sales and Supply of Sterile and Non Sterile Drug Eluting and Bare Metal Vascular Stents and Stents Systems, Inflation Device, PTCA & PTA Balloon Dilatation Catheters, PTCA and PTA Guide Wires, Aspiration Catheters, Sinuplasty System, Occluder and Delivery Systems, Angiokit, Drug Eluting PTCA and PTA Balloon Dilatation Catheters, Drug Eluting Bioresorbable Vascular Scaffold System, Intra-Aortic Balloon Catheters, Liquid Embolic System, Vascular Closure Device, Bare Metal and Drug Eluting Self Expanding Peripheral Stent System and Transcatheter and Surgical Heart Valve Systems.

Place and date:
Høvik, 26 November 2020

NORWEGIAN ACCREDITATION

MSYS 018

For:
DNV GL PRESAFE AS

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
ACCREDITED UNIT: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-20-695

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

KIMAL Plc

Arundel Road, Uxbridge, Middlesex, UB8 2SA United Kingdom

Products: Sterile Fluid Management Devices, Sterile Textiles and Drapes, Procedure Packs, KFlow Peritoneal Dialysis Catheters & Kits, AngioGATE Introducer Kits, Catheters Insertion Components, Introducer Needles, Kimal Vessel Dilator, Altius RT Acute Short Term Haemodialysis Catheter Kits, K Flow Epic Short Term Haemodialysis Catheter & Kits, Midline Catheters Kits, Extracorporeal Circuits, Connectors and Valves For Fluid Management, Manometer Lines, Drainage Sets, Surgical Instruments, Altius Central Venous Catheter (CVC) Sets, K Flow Epic Long-Term Haemodialysis Catheters & Kits, Peripherally Inserted Central Catheters (PICCs), AngioFLEX Guidewires

The products defined at the enclosure which is the part of this certificate and contains four (4) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number:	M.5872.01
Date of first issue:	05 September 2020
Date of last issue:	25 February 2021
Revision Number:	03
Expiry Date:	27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-695, Revision Number: 03

Concerned medical devices;

Product: Sterile Fluid Management Devices (KSP-213)

(KSP-213A) Sterile Accessory Devices&Mini Procedure Sets (Dialysis)
(KSP-213B) Sterile External Drainage Sets and Holding Devices

Product: Sterile Textiles and Drapes (KSP-216)

Product: Procedure Packs (KSP-215)

(KSP-215A) Cardiovascular Procedure Packs
(KSP-215D) Radiology Procedure Packs
(KSP-215C) Dialysis Procedure Packs
(KSP-215B) General Surgery Procedure Packs

Product: KFlow Peritoneal Dialysis Catheters & Kits (KSP-024)

Product: AngioGATE Introducer Kits (KSP-098)

Product: Catheters Insertion Components (KSP-194)

(KSP-194A) Altius Guidewires & Dispensers
(KSP-194B) Kimal Guidewires & Dispensers

Product: Introducer Needles (KSP-071)

Product: Kimal Vessel Dilator (KSP-049)

Product: Altius RT Acute Short-Term HD Catheter Kits (KSP-203)

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-695, Revision Number: 03

Concerned medical devices;

Product: KFlow Epic Short-Term Haemodialysis Catheter & Kits (KSP-132A)

Product: Midline Catheters Kits (KSP-200)

Product: Extracorporeal Circuits, Connectors and Valves for Fluid Management (KSP-212)

(KSP-212A) Angioflex Extension Lines
(KSP-212E) Connectors
(KSP-212D) Contrast Media Lines
(KSP-212F) KFE Connectors and Repair Valves
(KSP-212C) Manifolds and Manifold Sets
(KSP-212B) Stopcocks
(KSP-212H) Accessories
(KSP-212G) Syringes

Product: Manometer Lines (KSP-125)

Product: Procedure Packs (KSP-107)

(KSP-107E) Dialysis Procedure Packs
(KSP-107D) General Surgery Procedure Packs
(KSP-107C) Cardiovascular Procedure Packs
(KSP-107B) Radiology Procedure Packs

Product: Drainage Sets (KSP-189)

Product: Surgical Instruments (KSP-201)

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-695, Revision Number: 03

Concerned medical devices;

Product: Altius Central Venous Catheter (CVC) Sets (KSP-155)

(KSP-155A) Altius Classic Central Venous Catheter Sets
(KSP-155B) Altius 2nd generation Central Venous Catheter Sets
(KSP-155C) Altius HP and High Flow Central Venous Catheter Sets
(KSP-155D) Altius ProActiv+ Central Venous Catheter Sets

Product: K Flow Epic Long-Term Haemodialysis Catheters & Kits (KSP-132B)

KFlow Epic Long-Term Haemodialysis Catheter Kits-Dual Lumen
KFlow Epic Long-Term Haemodialysis Catheter Kits-Dual Lumen With Side Holes
KFlow Epic Long-Term Haemodialysis Catheter Kits-Split Dual Lumen
KFlow Epic Long-Term Haemodialysis Catheter Kits-Split Dual Lumen With Side Holes
KFlow Epic Long-Term Haemodialysis Catheter Kits-Twin Cath
KFlow Epic Long-Term Haemodialysis Catheter Kits-Twin Cath With Side Holes
KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro
KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro With Side Holes
KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro Split
KFlow Epic Long-Term Haemodialysis Catheter Kits-Retro Split With Side Holes

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
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Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3
Certificate Number: 1984-MDD-20-695, Revision Number: 03

Concerned medical devices;

Product: Peripherally Inserted Central Catheters (PICCs) (KSP-198)

A.KIMAL PICC - (Pressure) 1. I.Over Dilator 2. II. Over Needle 3. III. KIMAL PICC - (Catheter Only)
B. KIMAL PICC - (Catheter Over Dilator Rawlinson Set)
C. KIMAL PICC - (Catheter Over Dilator Brazil Set)
D. KIMAL PICC - (Non-Pressure - Reverse Taper) I. Over Dilator II. Over Needle

Product: AngioFLEX guidewires(KSP-217)

AngioFLEX uncoated stainless steel guidewires
AngioFLEX Teflon coated guidewires
AngioFLEX Hydrophilic coated guidewires

List of Critical Suppliers:	
Location	**Activity**
Kimal Medical Technologies Plot No. 16, Block E, Nasr City Free Zone, Cairo, Egypt.	Manufacturing, ethylene oxide sterilisation and logistics for KFlow Epic Short-Term Haemodialysis Catheters & Kits, Altius RT Haemodialysis Catheters Kits, Midlines Catheters Kits, Altius Central Venous Catheter (CVC) Sets, KFlow Epic Long-Term Haemodialysis Catheters & Kits, Peripherally Inserted Central Catheters (PICCs), Guidewires, connectors, valves and small packs.

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

25 February 2021, Istanbul, Turkey

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