EU Declaration of Conformity
Medical Device Regulation 2017/745

For the following products:

Disposable Non-invasive EEG Sensor
(Product Name)

See attachment 1
(Model Designation)

We herewith declare that the device(s) that is covered by the present declaration is in conformity with Medical Device Regulation 2017/745.This declaration of conformity is issued under the sole responsibility of the manufacturer.

Applicable harmonized standards are:

ANSI/AAMI EC12-2000(R2020), EN ISO 20417:2021, ISO 20417:2021, EN ISO 15223-1:2021, ISO 15223-1:2021, EN ISO 10993-1:2020, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-5:2009, EN ISO 10993-10:2010, ISO 10993-10:2010, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, ISO 14971:2019

Conformity Assessment Route:

Medical Device Regulation 2017/745 annex II&III,IV CE

Classification: Class I, Rule 1

Basic UDI-DI: 69444140004SL

European Authorized Representative:

Company Name: Shanghai International Holding Corp. GmbH (Europe)
Company Address: Eiffestrasse 80, 20537 Hamburg, Germany
SRN: DE-AR-000000001

Manufacturer:

Company Name: Shenzhen Med-link Electronics Tech Co.,Ltd.
Company Address: 2nd, 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA.
SRN: CN-MF-000011145

Signature:

Maolin Ye, General Manager
Name, position

Place, Date of Issue: Shenzhen City, 19th Jun., 2024

Attachment 1 -- Model list

Model No.
Disposable Noninvasive EEG Sensor: B-BIS-6A, B-BIS-6A-01, B-BIS-6A-02, B-BIS-6A-03, B-BIS-5A, B-BIS-5A-01, B-BIS-4A, B-BIS-4P, B-BIS-4P-01, B-BIS-3A, B-BIS-4A-01, B-BIS-3A-01, B-BIS-3A-02, B-BIS-3A-03, B-BIS-3AL, B-BIS-3AL-01, B-BIS-3AR, B-BIS-3AR-01
Disposable Noninvasive EEG Sensor cable: B0052A, B0051A, B0050I, B0050A, B143-P-10-60

Catalogue No.
OBM-99030309-01, 9902040901, 9902040502, 9902060901, 9903030901, OEM-B3681A, OEM-B3998A, OEM-B3327D, OEM-B3327C, OEM-B3280A, OEM-B1304A, OEM-B3327B, OEM-3852B, OEM-B1304B, OEM-B3327A, OEM-3852A, B0054A, 9902040904, 9902040504, 9902060902, OBM-B0287A

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DNV

Notified Body Confirmation Letter Reference: C611945

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Bio Protech Inc.

Donghwa Medical Instrument Complex, 151-3, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

SRN Number: KR-MF-000012687

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 2023/08/11

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

C. Rajesh Kumar

Rajesh Kumar Chellappan
Management Representative

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- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Electrosurgical Unit Plates • PROPLATE, Horizontal • PROPLATE, Vertical / Basic UDI-DI: 880908394090L4	Class IIb	NA	Certificate No:10316-2017-CE-KOR-NA-PS Rev. 1.0; NB Number: 2460
Electrosurgical Unit Pencils • PROPENCIL /Basic UDI-DI: 880908394100KE	Class IIb	NA	Certificate No:10316-2017-CE-KOR-NA-PS Rev. 1.0; NB Number: 2460
Smoke Evacuation Pencils • PROPENCIL /Basic UDI-DI: 880908394110KH	Class IIb	NA	Certificate No:10316-2017-CE-KOR-NA-PS Rev. 1.0; NB Number: 2460
Needle Electrodes • Disposable Monopolar Needle Electrodes • Disposable Concentric Needle Electrodes • Disposable Hypodermic Needle Electrodes • Disposable EP Needle Electrodes / Basic UDI-DI: 880908394070KW	Class IIa	NA	Certificate No:10316-2017-CE-KOR-NA-PS Rev. 1.0; NB Number: 2460

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/08/11	C611945	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe

aspensurgical

EU Declaration of Conformity to MDR

MANUFACTURER		
Name of company	**Address**	**SRN**
Aspen Surgical Products, Inc.	6945 Southbelt Drive SE Caledonia, Michigan 49316, USA	US-MF-000008255

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Securline Taper Tip Marker and Ruler Set	1000-00-PDG
Securline Taper Tip Marker and Ruler Set	1002-00-PDG
Securline Taper Tip Marker, Ruler and Label Set	100L-00-PDG
Fine Tip Marker, Ruler and Label Set	2630
Regular Tip Marker with Ruler and 6-Up Labels	2650
Writesite Plus Prep Resistant Skin Marker (EU), Regular Tip	2700-I
Chloraprep Resistant Marker with Ruler	2710
WriteSite Plus Multi-Ink Prep Resistant Skin/Utility Marker, Regular Tip, with Ruler and 6 Labels	2720
Modern Fine Tip Maker, Ruler and Label Set	2730
Regular Tip Marker, Ruler and Label Set	2750
Regular Style Pen with Ruler and Labels	2750OEMDSP
WriteSite Multi-Ink Marker	2755
Dual Tip Skin Marker	2777
Taper Tip Skin Marker with Ruler and Labels	900-7019
Taper Fine Tip Pen with Ruler	AMS1000
Classic Regular Tip Marker	G2651
Modern Fine Tip Marker	G2731
Modern Style, Reg Tip, Pen & Ruler (DYNJSM01)	MD-2003
Modern Regular Tip Pen w/Ruler & 6-Up Labels (DYNJSM02)	MD-2004
Classic Style Fine Tip, Pen & Ruler (DYNJSM03)	MD-2005
Modern Fine Tip Pen, Ruler and Labels	SM0372
Modern Regular Tip Pen with Ruler	SM0572
Surgical Marking Pen Fine Tip	19004-01CE
Surgical Marking Pen Fine Tip with Ruler	19004-02CE
Surgical Marking Pen Fine Tip with Ruler and Labels	19004-03CE
Surgical Marking Pen Regular Tip	19005-01CE
Surgical Marking Pen Regular Tip with Ruler	19005-02CE
Surgical Marking Pen Regular Tip with Ruler and Labels	19005-03CE
Intended Purpose	**Basic UDI-DI**
Surgical Marking Pens are intended for surgical marking on intact skin.	0840113240000ST4C

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aspen surgical

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	1s	ISO 13485:2016
Rule:	1	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands	2797	Annex XI Part A of MDR 2017/745 Regulation	MDR 755274

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. Aspen Surgical Products, Inc. declares that the above-mentioned products meet the relevant requirements of the EU Medical Device Regulation 2017/745.

COMPANY REPRESENTATIVE: Stephanie Sullivan

TITLE: Regulatory Affairs Manager **SIGNATURE:** Stephanie Sullivan

Digitally signed by Stephanie Sullivan
Date: 2023.12.21 12:07:01 -05'00'

PLACE: Caledonia, Michigan USA **DATE:** December 21, 2023

Direktc
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 005322 0004 Rev. 00

Manufacturer: **MoNo chem-pharm Produkte GmbH**
Leystraße 129
1200 Wien
AUSTRIA

SRN Manufacturer: AT-MF-000000282

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 005322 0004 Rev. 00

Report No.: 713261915

Valid from: 2023-03-17
Valid until: 2028-03-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-03-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 005322 0004 Rev. 00

Classification:	Class IIa
Device Group:	D0899 - DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2023-03-17	713261915	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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LIETUVOS UAB "EX BALTIC" RESPUBLIKA

ITALCERT S.r.l.
viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 - fax +39 0266101479
E- mail italcert@italcert.it

Notified Body n° 0426

CERTIFICATE N° 166-02-00-DM

(in compliance with Annex V of the Directive 93/42/EEC)

ITALCERT

certifies that the

Production Quality Assurance System
applied for the manufacture and final inspection
of "Medical Devices" - MD -
by the manufacturer

M.D.L. S.r.l.

via Tavani, 1/a - 23014 DELEBIO (SO) - ITALY

in the headquarters located in

via Tavani, 1/a
23014 DELEBIO (SO) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex V

and authorizes the manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito
MANAGING DIRECTOR

First Issue date	Renewal date	Expire date
2011-04-29	2018-12-20	2023-12-19

This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n° 166-02-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

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M.D.L. Srl
Via Tavani 1/a – 23014 – Delebio (So) - Italy
Tel (+39) 0342 / 682130 Fax (+39) 0342 / 691316
P.IVA e Cod. Fiscale 00656810140 Cod. Rea : 46278
e_mail: info@mdlsrl.com web:www.mdlsrl.com

Subject:

"LEGACY DEVICE" Declaration - REGULATION (EU) 2023/607
Extension of the expiry date of the CE Certificate No. 166-02-03-DM

The undersigned M.D.L. S.r.l. (SRN: IT-MF-000011599), having its registered office in Via Tavani 1/A - 23014 Delebio (SO) - Italy, declares under its sole responsibility that the medical devices listed in the CE Certificate No. 166-02-03-DM (expire date 19/12/2023) issued by the Notified Body "Italcert S.r.l." (No. 0426), are in accordance with REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

The CE Certificate No. 166-02-03-DM is therefore valid beyond its natural expiry date until 26th May 2024 for all the medical device codes listed in it.

After 26th May 2024 the CE Certificate will be valid at least for the codes listed in the table below until 31st December 2028:

Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PILXXYY/ZZ	Illy	IIa	IIa
PJXXYY	OsteoJ	IIa	IIa
PJHXXYY	OsteoJ, OsteoJH	IIa	IIa
PIXXYY/ZZ	PenBone	IIa	IIa
PIGXXYY/ZZ	Pen-Bone	IIa	IIa
PIPXXYY/ZZ	PenBone Blu	IIa	IIa
PJTXXYY	PickUp	IIa	IIa
PJTHXXYY	PickUp, Pick-Up	IIa	IIa
PJTDXXYY	PickUpD	IIa	IIa
PJK2XXYY	JamBlu	IIa	IIa
PJK2HXXYY	JamBlu	IIa	IIa
PSXXYY	PressTo	IIa	IIa
PSH1D2XXYY	CellColt	IIa	IIa
PJEXXYY	Harvest	IIa	IIa
PIEXXYY/ZZ	PenBoneE	IIa	IIa

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M.D.L. Srl
Via Tavani 1/a – 23014 – Delebio (So) - Italy
Tel (+39) 0342 / 682130 Fax (+39) 0342 / 691316
P.IVA e Cod. Fiscale 00656810140 Cod. Rea : 46278
e_mail: info@mdlsrl.com web:www.mdlsrl.com

Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PILEXXYY/ZZ	IllyE	IIa	IIa
PC0XXYY	EasyCut	IIa	IIa
PCXXYY	EasyLock	IIa	IIa
PMXXYY	HandCut	IIa	IIa
PAXXYY	EpaSet	IIa	IIa
VEXXYY	MDCut E, FastCutE	IIa	IIa
VESXXYY	FastCutS	IIa	IIa
MGXXYY	FastCutM	IIa	IIa
MGPXXYY	MDCut P, FastCutP	IIa	IIa
MGPCXXYY	FastCutP	IIa	IIa
MGK1XXYY	Palium Needle	IIa	IIa
MGCXXYY	Palium Needle, PaliumCoaxial	IIa	IIa
PDXXYY	LightCut Plus	IIa	IIa
PD0XXYY	SemiCut	IIa	IIa
PD0MRXXYY	SemiCut MRI	IIa	IIa
PD0PPXXYY	SemiCut, SemiCut Coax.	IIa	IIa
TYXXYY	Themy	IIa	IIa
TYSXXYY	ThemyS	IIa	IIa
TYSCXXYY	ThemySC	IIa	IIa
TYCXXYY	Themy, ThemyC	IIa	IIa
TYQXXYY	ThemyQ	IIa	IIa
TYQCXXYY	ThemyQC	IIa	IIa
PTXXYY	Intro	IIa	IIa
PTMXXYY	Intro	IIa	IIa
PL	Palium	IIa	IIa
PBXXYY	CytoCut	IIa	IIa
PBMXXYY	CytoCut	IIa	IIa
PBQXXYY	CytoCut	IIa	IIa
PBUXXYY	Amnio	IIa	IIa
PBUTXXYY	ChorionSet	IIa	IIa
PEFXXYY	Franseen	IIa	IIa
PEWXXYY	Wescott	IIa	IIa
AETNXXYYY	StimyEcho	IIa	IIa
AETNFXXYYY	StimyEcho	IIa	IIa
AEQNXXYYY	StimyEcho	IIa	IIa
AEQNFXXYYY	StimyEcho	IIa	IIa
AEYNXXYYY	StimyEcho	IIa	IIa
AEYNFXXYYY	StimyEcho	IIa	IIa

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M.D.L. Srl
Via Tavani 1/a – 23014 – Delebio (So) - Italy
Tel (+39) 0342 / 682130 Fax (+39) 0342 / 691316
P.IVA e Cod. Fiscale 00656810140 Cod. Rea : 46278
e_mail: info@mdlsrl.com web:www.mdlsrl.com

Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
AETMNXXYYY	StimyEcho16	IIa	IIa
AEYMNXXYYY	StimyEcho20	IIa	IIa
AEQMNXXYYY	StimyEcho30	IIa	IIa
AETHXXYYY	StimyPlus	IIa	IIa
AETHFXXYYY	StimyPlus	IIa	IIa
AETMXXYYY	StimyPlus16	IIa	IIa
AEYMXXYYY	StimyPlus20	IIa	IIa
AEQMXXYYY	StimyPlus30	IIa	IIa
AEQHXXYYY	StimyPlus	IIa	IIa
AEQHFXXYYY	StimyPlus	IIa	IIa
AEYHXXYYY	StimyPlus	IIa	IIa
AEYHFXXYYY	StimyPlus	IIa	IIa
AETRXXYYY	StimyUltra, StimyUltra16	IIa	IIa
AETRFXXYYY	StimyUltra	IIa	IIa
AEQRXXYYY	StimyUltra, StimyUltra30	IIa	IIa
AEQRFXXYYY	StimyUltra	IIa	IIa
AEYRXXYYY	StimyUltra, StimyUltra20	IIa	IIa
AEYRFXXYYY	StimyUltra	IIa	IIa
AEYMVXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEQMVXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEYHVXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEQHVXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEYMVFXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEQMVFXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEYHVFXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEQHVFXXYYY	VygoPlex ENS & Echo	IIa	IIa
AEYMNVXXYYY	VygoPlex Echo	IIa	IIa
AEQMNVXXYYY	VygoPlex Echo	IIa	IIa
AEYNVXXYYY	VygoPlex Echo	IIa	IIa
AEQNVXXYYY	VygoPlex Echo	IIa	IIa
AEYMNVFXXYYY	VygoPlex Echo	IIa	IIa
AEQMNVFXXYYY	VygoPlex Echo	IIa	IIa
AEYNVFXXYYY	VygoPlex Echo	IIa	IIa
AEQNVFXXYYY	VygoPlex Echo	IIa	IIa
PNXXYY	Mark	IIa	IIa
PNXXXYY	MarkX	IIa	IIa

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M.D.L. Srl
Via Tavani 1/a – 23014 – Delebio (So) - Italy
Tel (+39) 0342 / 682130 Fax (+39) 0342 / 691316
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e_mail: info@mdlsrl.com web:www.mdlsrl.com

Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PNZXXYY	MarkZ	IIa	IIa
PNSXXYY	MarkSlim	IIa	IIa
PNAXXYY	AutoMark	IIa	IIa
PNAXXXYY	AutoMarkX	IIa	IIa
PRXXYY	RepoMark	IIa	IIa
PRDXXYY	RepoMarkD	IIa	IIa
AVAXXYY	VeressA	IIa	IIa
AVAQXXYY	VeressQ	IIa	IIa
AVBXXYY	VeressB	IIa	IIa
AVBQXXYY	VeressQ	IIa	IIa
AVCXXYY	VeressC	IIa	IIa
AVCQXXYY	VeressQ	IIa	IIa
AV01TXX	ToraSet	IIa	IIa
AV01XXYYA	ToraSet	IIa	IIa
AV01XXYYB	ToraSet	IIa	IIa
AV01XXYYC	ToraSet	IIa	IIa
AV02TXX	ToraSetValve	IIa	IIa
AV02XXYYA	ToraSetValve	IIa	IIa
AV02XXYYB	ToraSetValve	IIa	IIa
AV02XXYYC	ToraSetValve	IIa	IIa
AV01KS	ParaSet	IIa	IIa
AV02KS	ParaSet	IIa	IIa
PZYDXXYY	GalaKitDuo	IIa	IIa
PZYCXXYY	GalaKitDuo	IIa	IIa
RF0MXXYYYRZZα	RF Probe IE	IIa	IIa
RFXXYYYRZZα	RF Probe	IIa	IIa
LPXXYYRZ	Lipo	IIa	IIa
LPXXYYZ	Lipo	IIa	IIa

Delebio, 10.01.2024

Signature

M.D.L. SRL
Via Tavani, 1/A
23014 DELEBIO (SO), Italia

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CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2019.106.12774-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti.
Company Address	: Maliköy Mah. Başkent Osb 19. Cad. No:54 Sincan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Oxidized Regenerated Cellulose - Class III Sterile Polypropylene Mesh - Class IIb
GMDN	: 60300, 58298
	Product Types are attached.
Certificate Number	: M.2019.106.12774
Report Number	: MD.3902.IB
Initial Assessment Date	: 18.09.2019
Registration Date	: 16.10.2019
Revision Date /No	: -
Expiry Date	: 27.05.2024

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and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II section 5 of the forementioned directive. According to Annex II section 4 an EC design examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile, and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr

Addrres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

Direktorius
Paulius Šulte
KOPIJA TIKRA
UAB "MEDEX BALTIC"

This document containing 2 (two) pages is the Annex of the Certificate with the number M.2019.106. 12774 and with the registration date of 16.10.2019 issued for "Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices

ABSORBABLE HEMOSTATS (Oxidized Regenerated Cellulose)		
Pahacel® Standard Absorbable Hemostat		
Reference	**Size**	**Description**
PCS11	1,25 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS12	1,3 cm x 5,1 cm	Pahacel® Standard Absorbable Hemostat
PCS13	1,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS14	2,5 cm x 2,5 cm	Pahacel® Standard Absorbable Hemostat
PCS15	2,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS16	5 cm x 7,5 cm	Pahacel® Standard Absorbable Hemostat
PCS17	5 cm x 35 cm	Pahacel® Standard Absorbable Hemostat
PCS18	5,1 cm x 7,6 cm	Pahacel® Standard Absorbable Hemostat
PCS19	5,1 cm x 35,6 cm	Pahacel® Standard Absorbable Hemostat
PCS20	7,5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
PCS21	10 cm x 20 cm	Pahacel® Standard Absorbable Hemostat
PCS22	10,2 cm x 20,3 cm	Pahacel® Standard Absorbable Hemostat
PCS23	15 cm x 23 cm	Pahacel® Standard Absorbable Hemostat
PCS24	12,5 cm x 5 cm	Pahacel® Standard Absorbable Hemostat
PCS25	5 cm x 10 cm	Pahacel® Standard Absorbable Hemostat
Pahacel® Knit Absorbable Hemostat		
Reference	**Size**	**Description**
PCK11	2,6 cm x 2,6 cm	Pahacel® Knit Absorbable Hemostat
PCK12	7,6 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK13	15,2 cm x 22,9 cm	Pahacel® Knit Absorbable Hemostat
PCK14	2,5 cm x 5,1 cm	Pahacel® Knit Absorbable Hemostat
PCK15	5,1 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK16	10,2 cm x 10,2 cm	Pahacel® Knit Absorbable Hemostat
PCK17	5 cm x 7,5 cm	Pahacel® Knit Absorbable Hemostat
Pahacel® Fibril Absorbable Hemostat		
Reference	**Size**	**Description**
PCF11	2,6 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF12	7,6 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF13	15,2 cm x 22,9 cm	Pahacel® Fibril Absorbable Hemostat
PCF14	2,5 cm x 5,1 cm	Pahacel® Fibril Absorbable Hemostat
PCF15	5,1 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF16	10,2 cm x 10,2 cm	Pahacel® Fibril Absorbable Hemostat
PCF17	5 cm x 7,5 cm	Pahacel® Fibril Absorbable Hemostat
Pahacel® Pillow Type Absorbable Hemostat (For Extra Hemostasis)		
Reference	**Size**	**Description**
PCE11	3 cm x 3 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE12	5 cm x 5 cm	Pahacel® Pillow Type Absorbable Hemostat
PCE13	5 cm x 7,5 cm	Pahacel® Pillow Type Absorbable Hemostat
Polypropylene Mesh – Standard Type		
Order No	**Size**	
P1010	10x10 cm	

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

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This document containing 2 (two) pages is the Annex of the Certificate with the number M.2019.106. 12774 and with the registration date of 16.10.2019 issued for "Altaylar Medikal Tıbbi Malzeme İnşaat Tekstil Gıda İthalat İhracat Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices

P1013	10x13 cm
P2235	22x35 cm
P1020	10x20 cm
P1520	15x20 cm
P0813	8x13 cm
P1015	10x15 cm
P1515	15x15 cm
P1530	15x30 cm
P0220	2x20 cm
P2020	20x20 cm
P2030	20x30 cm
P2525	25x25 cm
P2535	25x35 cm
P3030	30x30 cm
P0510	5x10 cm
P0520	5x20 cm
P0611	6x11 cm
P0614	6x14 cm
P7515	7,5x15 cm
P0815	8x15 cm
P0914	9x14 cm
P4545	45x45 cm
Polypropylene Mesh - Pre - Cut Shapes	
Order No	**Size**
PP0505	5x5 cm
PP0707	7x7 cm
PP0505-H	5x5 cm
PP0707-H	7x7 cm
PP4510	4,5x10 cm
PP0611	6x11 cm
PP4510-H	4,5x10 cm
PP0611-H	6x11 cm
PP75125	7,5x12,5 cm
PP8515	8,5x15 cm
PP1515	15x15 cm

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co

Direkt
Paulius
KOPIJA

UAB "FEDEX BALTIC" LIETUVOS RESPUBLIKA

UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2024/01/29

Altaylar Medikal Tıbbi Malzemeleri İnşaat Tekstil
Gida İthalat İhracat Sanayi ve Ticaret Ltd. Şti.
Maliköy Mah. Başkent OSB 19.Cad. No:54
Sincan, Ankara, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2024.MDR.1578.NBCL.0064

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2022/09/30) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/09/30) with the following manufacturer:

Altaylar Medikal Tıbbi Malzemeleri İnşaat Tekstil
Gida İthalat İhracat Sanayi Ve Ticaret Ltd. Şti.
Maliköy Mah. Başkent OSB 19.Cad. No:54
Sincan, Ankara, Türkiye
SRN Number (if available): TR-MF-000021519

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
OIB:50373079784

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In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ
General Manager

UDEM Adriatic d.o.o.
Radnička cesta 54/R3, Green Gold

UDEM Adriatic d.o.o.

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Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Polypropylene Mesh P900202/ 869898587TD012K	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.12774 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Oxidized Regenerated Cellulose M040501/ 869898587TD02-S3G ORC Std, rule 8 **869898587TD02-F2N ORC Fibril** **869898587TD02-K2Y ORC Knit** **869898587TD02-P3A ORC Pillow**	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.12774 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design-Examination Certificate No: M.2019.106.12774-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

UDEM Adriatic d.o.o.
UDEM OIB:50373079764
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb

UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb
Phone: +385 (1) 4819 601• **Fax:** +385 (1) 4819 434
E-mail: info@udemadriatic.com

www.udemadriatic.com

Direkto
Paulius
KOPIJ

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UAB "EDEX BALTIC"

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/29	2024.MDR.1578.NBCL.0064	Initial issue

UDEM Adriatic d.o.o.
UDEM OIB:5[illegible] agreb
Radnička cesta 54/[illegible]
Tel:(1)4[illegible]
www

UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb
Phone: +385 (1) 4819 601• **Fax:** +385 (1) 4819 434
E-mail: info@udemadriatic.com

www.udemadriatic.com

[redacted]

Di[illegible]
Pa[illegible]
K[illegible]

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Neuromedex GmbH
Manufacturer address and contact details	Vierenkamp 15, 22453 Hamburg – Germany contact@neuromedex.com
Single Registration Number (SRN) (if available)	DE-MF-000005867

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	x See attached schedule
Notified body number (if applicable)	x See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
D 22453 Hamburg

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

USt-IdNr. DE 118647409
Amtsgericht Hamburg
HRB 19038

Geschäftsführer
Marco Geyer
Markus Drewes

Direkt
Paulius
KOPIJA

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Directive Certificate number(s) to which this confirmation is made (if applicable)	x See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	x See attached schedule
End date of extended validity/transition period	x See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ✓ Expired *before* 20 March 2023:
  - ✓ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
D 22453 Hamburg

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

USt-IdNr. DE 118647409
Amtsgericht Hamburg
HRB 19038

Geschäftsführer
Marco Geyer
Markus Drewes

Direktor
Paulius
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Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

✓ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ✓ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ✓ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
D 22453 Hamburg

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

USt-IdNr. DE 118647409
Amtsgericht Hamburg
HRB 19038

Geschäftsführer
Marco Geyer
Markus Drewes

Direktor
Paulius Š
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➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Neuromedex GmbH

Location & Date: Hamb 1-05-28

Signature, Print Name, Title: Victor Head of Quality Management

Contact Details (at least email): cont romedex.com

NEUROMEDEX®

Neuromedex GmbH
Vierenkamp 15
D 22453 Hamburg

phone +49 (0)40 696 564 100
fax +49 (0)40 696 564 200
web www.neuromedex.com

Hamburger Volksbank eG
IBAN DE04 2019 0003 0019 5623 06
BIC GENODEF1HH2

USt-IdNr. DE 118647409
Amtsgericht Hamburg
HRB 19038

Geschäftsführer
Marco Geyer
Markus Drewes

Direktorius
Paulius Šu

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Catheter ventricular antimicrobial	10554DE411190607 10554GB411190607	2022-07-19	Medcert 0482	DNV Medcert 0482	2027-12-31	Not applicable
Catheter ventricular	10554DE411200428 10554GB411200428	2024-05-27	Medcert 0482	DNV Medcert 0482	2027-12-31	Not applicable
Catheter lumbar antimicrobial	10554DE411190607 10554GB411190607	2022-07-19	Medcert 0482	DNV Medcert 0482	2027-12-31	Not applicable
Catheter lumbar	10554DE411200428 10554GB411200428	2024-05-27	Medcert 0482	DNV Medcert 0482	2027-12-31	Not applicable
Brain biopsy canula	10555DE411200428 10555GB411200428	2024-05-27	Medcert 0482	DNV Medcert 0482	2027-12-31	Not applicable
Sternal wire	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
VentrEX Complete, VentrEX, EVD System	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Transpapillary stents, Pusher, Guiding, PSI	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Wound drainage catheters	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Occlusion catheters	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Suction canula	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Mediloops	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Medipaws	1261DE410200408 1261GB410200408	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Navigation marker Spheres	1261DE415190607 1261GB415190607	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Cautery Tip Cleaner	1261DE415190607 1261GB415190607	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable
Drainage bags, Reservoirs, Replacement components for CSF-drainage, Connectors	1261DE415190607 1261GB415190607	2024-05-27	Medcert 0482	DNV Medcert 0482	2028-12-31	Not applicable

Direktor
Paulius Š
KOPIJA T

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"MEDEX BALTIC"
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DNV

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2024-05-24

Our reference: QS-1261 / PP-10544 / PP-10555

Notified Body Confirmation Letter
Certification No: 1261GB454240524

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

Neuromedex GmbH
Vierenkamp 15
22453 Hamburg
Germany
SRN[2]: DE-MF-000005867

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.

[2] Single registration number (SRN) according to Article 31 (2) of MDR.

Instruments and equipment covers	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Non-absorbable non-synthetic sutures	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
426002751140-071-1P8	Class III	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482 10555DE411200428 NB 0482 10555GB411200428 NB 0482
426002751020-069-1NC	Class III	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482 10554DE413200428 NB 0482 10554GB411200428 NB 0482 10554DE411190607 NB 0482 10554GB411190607 NB 0482

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-02-01	1261GB454240201	Initial issue
2024-05-24	1261GB454240524	Addition of IIa for MDN1202 + MDN1203 (Vascular occlusion catheters)

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
General non-active non-implantable devices used in health care and other non-active non implantable devices	Class I devices placed on the market in sterile condition	N/A	Certificate 1261DE415190607 NB 0482 1261GB415190607 NB 0482
Non-active non-implantable devices for anaesthesia, emergency and intensive care	Class I devices placed on the market in sterile condition	N/A	Certificate 1261DE415190607 NB 0482 1261GB415190607 NB 0482
Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Class I devices placed on the market in sterile condition	N/A	Certificate 1261DE415190607 NB 0482 1261GB415190607 NB 0482
Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Vascular occlusion catheters	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Surgical drainage systems	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Tapes, medical/surgical	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482
Cranial drainage devices and kits	Class IIa	N/A	Certificate 1261DE410200408 NB 0482 1261GB410200408 NB 0482

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history