Digitally signed by Ostapciuc Alexandr
Date: 2023.10.09 11:38:58 EEST
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Location: Moldova

EC CERTIFICATE

Full Quality Assurance System

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

M.2021.106.14633-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: NeuroSafe Medical Co.,Ltd.
Company Address	: Building B, No. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone, Zhuhai, Guangdong, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Dredger Revascularization Device - Class III Sterile Lava Liquid Embolic System - Class III Sterile Glutton Aspiration Catheter - Class III
GMDN	: 61779, 35449, 58173
	Product Types are attached.
Certificate Number	: M.2021.106.14633
Report Number	: MD.4109.IB
Initial Assessment Date	: 26.03.2021
Registration Date	: 25.05.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry 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 applies 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 sertificate 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2021.106.14633 and with the registration date of 25.05.2021 issued for "NeuroSafe Medical Co.,Ltd." 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 Directive.

Glutton Aspiration Catheter, Class III, GMDN Code: 58173 Embolectomy/thrombectomy suction catheter, Brand Name：Glutton
Models:

Model	Fr. Size	Inner Diameter (inch)	Outer Diameter (inch)	Effective Length (cm)	Contents
5F-115	5F	0.058	0.070	115	1 x Aspiration Catheter, 1 x Introducer Sheath, 1 x Shaping Mandrel.
5F-125	5F	0.058	0.070	125	
5F-132	5F	0.058	0.070	132	
6F-105	6F	0.073	0.085	105	
6F-115	6F	0.073	0.085	115	
6F-125	6F	0.073	0.085	125	
6F-115BGC	6F	0.070	0.082	115	
6F-125BGC	6F	0.070	0.082	125	
6F-132BGC	6F	0.070	0.082	132	
6F-115S	6F	0.073	0.085	115	
6F-125S	6F	0.073	0.085	125	
6F-132S	6F	0.073	0.085	132	

Dredger Revascularization Device, Class III, GMDN Code：61779 Thrombectomy wire-net, Brand Name：Dredger
Models:

Model	Diameter (mm)	Effective length (mm)	Contents
RD-3-20	3	20	1 x Revascularization Device
RD-3-30	3	30	
RD-4-20	4	20	
RD-4-30	4	30	
RD-4-40	4	40	
RD-5-20	5	20	
RD-5-30	5	30	
RD-5-40	5	40	
RD-6-24	6	24	
RD-6-30	6	30	
RD-6-42	6	42	
RD-7-30	7	30	
RD-7-42	7	42	

Lava Liquid Embolic System, Class III, GMDN Code：35449 Prosthesis, Internal, Embolization, Intravascular, Brand Name：Lava
Models:

Model	Viscosity (@25°C) (mm^2/s)	Contents
LAVA-12	12	1 x 1.5 mL Liquid Embolic Agent, 1 x 1.5 mL DMSO, 3 x 1 mL Syringe.
LAVA-18	18	
LAVA-34	34	

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

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name	: Neurosafe Medical Co., Ltd.
Company Address	: Building B, No. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone, Zhuhai, Guangdong, China
Related Directive	: 93/42/EEC Medical Devices Directive
Definition of Change	: GMDN code has been changed from 35449 to 60939.

Number of Related Certificate	: M.2021.106.14633, M.2021.106.14633-1
Report Number	: MD.4109
Issue Date	: 07.06.2022
Revision Date	: -
Revision Number	: 00

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120 (3) and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

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