Digitally signed by Ostapciuc Alexandr
Date: 2023.10.09 11:39:24 EEST
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Location: Moldova

EC DESIGN EXAMINATION CERTIFICATE

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2021.106.14633 the validity of the certificate M.2021.106.14633-1 will also end.

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 (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.2021.106.14633-1
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.

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, 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 aforementioned directive. 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 expiry date 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.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
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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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