NEUROSAFE

Declaration of Conformity

Product Name:	Liquid Embolic System
Trade Name:	Lava
Classification:	Class III (93/42/EEC MDD, Annex IX, Rule 6)
Basic UDI-DI:	Refer to product schedule
Conformity Assessment Method:	93/42/EEC Medical Devices Directive -Annex II （Section 4）
GMDN Code:	60939
Manufacturer:	Name: NeuroSafe Medical Co., Ltd. Address: Building B, No. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone, Zhuhai, Guangdong, 519 000, China
EU Authorized Representative:	Name: CMC Medical Device & Drugs S. L. Address: C/Horacio Lengo 18, CP 29006, Málaga, Spain
Notified Body:	Name: UDEM International Certification Inc. Co. Identification No. : 2292
EC Certificates:	EC Certificate No. : M.2021.106.14633 EC Design Examination Certificate No. : M.2021.106.14633-1
CE marking start date	May 25, 2021
Related Directives and Annex:	93/42/EEC Medical Devices Directive-Annex II

We hereby declare that this declaration of conformity is issued under the sole responsibility of NeuroSafe Medical Co., Ltd.. The distributed CE marked products, as specified on the below product schedule, are covered by the "CE marking of Conformity Certificate", and delivered by Notified Body "UDEM". All products on the product schedule meet the provisions of the above mentioned 93/42/EEC Medical Devices Directive (2007/47/EC), and conform to the required technical documentation, in accordance with Annex II of 93/42/EEC Medical Devices Directive (2007/47/EC).

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.09 11:37:03 EEST
Reason: MoldSign Signature
Location: Moldova

Product Schedule

Catalog No.	Viscosity (cst)	Basic UDI-DI
LAVA-12	12	0697374657000 4
LAVA-18	18	0697374657001 1
LAVA-34	34	0697374657002 8

Authorized Representative: Hai Guo Title: QA/RA Director

Signature: Hai Guo Place & Date: 2023.8.8