Digitally signed by Bolea Petru
Date: 2021.07.01 12:03:50 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

Neitz Instruments Co., Ltd.
4F Ichibancho Court, 15-21
Ichibancho,
102-0082 Chiyoda-ku, Tokyo
JAPAN

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2021-06-07

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 408534

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
NTF-10100001-01	Direct Ophthalmoscopes	46786	I	MDR09-10100001E-02 signed 2021-03-30	N.A.	N.A.	DE/CA09/0170/N14/005-02
NTF-10410001-01	Monocular Indirect Ophthalmoscope	46788	I	MDR09-10410001E-03 signed 2021-03-15	N.A.	N.A.	DE/CA09/0170/N14/007
NTF-10800001-01	Binocular Indirect Ophthalmoscopes	46790	I	MDR09-10800001E-01 signed 2021-03-22	N.A.	N.A.	DE/CA09/0170/N14/006-01
NTF-10900001-01	Retinoscopes	32712	I	MDR09-10900001E-02 signed 2021-03-30	N.A.	N.A.	DE/CA09/0170/N14/004-02
NTF-11000001-01	Binocular Loupes	32692	I	MDR09-11000001E-03 signed 2020-12-10	N.A.	N.A.	DE/CA09/0170/N14/001-02
NTF-14010001-01	Spot Illuminator (Headlight)	11963	I	MDR09-14010001E-01 signed 2021-03-22	N.A.	N.A.	DE/CA09/0170/N14/002-02

*The registration number has been issued by the German Competent Authority.