Declaration of System Conformity
nëo monitor system [ES-820] *version 1.4*

Hereby we declare that below identified combination of products have been verified for mutual compatibility in accordance with the manufacturers' instructions and intended uses.

nëo monitor [LE-800] (software)
Product version 1.4, CE marked according to MDD 93/42/EEC[1], CE class IIa,
Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany

eego amplifier [EE-411] [EE-511]
Product version 1.0, CE marked according to MDD 93/42/EEC[1], CE class IIa, Directive 2011/65/EU
Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany

Mounting plate [M02281]
Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany

All-In-One Computer "OR-PC® 15" [M02334]
CE marked according to Directives 2014/35/EU, 2014/30/EU, 2011/65/EU and compliant with DIN EN 60601-1:2013 and DIN EN 60601-1-2:2016
Manufactured by ACL GmbH, Markkleeberg, Germany

With compatible accessories:

EEG touchproof adapter [XC-810], adapter [XC-425]
CE marked according to MDR 2017/745, CE class I,
Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany

waveguard original cap [CA-42x], sizes N1, N2, N3, N4, N5, B, I, C
CE marked according to MDR 2017/745, CE class I, Directive 2011/65/EU
Manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany

Mobile Cart "vexio-cart plus 35E" [XC-820]
CE marked according to MDR 2017/745, CE class I
Manufactured by ITD GmbH, Johanniskirchen, Germany

The system is packaged and supplied with relevant user information incorporating relevant instructions from the manufacturers.

Product design, development and testing have been performed to comply with the standards set by internal procedures as officially in use at *eemagine Medical Imaging Solutions GmbH*.

We are registered with HIBCC, with *Labeler Identification Code* (LIC): B195.
EUDAMED assigned our Single Registration Number (SRN): DE-MF-000005560.

[1] Regulation (EU) 2017/745 (MDR), Article 120 applies (transitional provisions).
The nëo monitor system is manufactured in line with Article 22 of MDR 2017/745.

Dated at Berlin, Germany, on the _22nd___ day of ____May_____ 2024.

Frank Zanow, CEO
eemagine Medical Imaging Solutions GmbH
Gubener Straße 47, D-10243 Berlin, Germany

Product list appended to the Declaration of System Conformity
nëo monitor system [ES-820] version 1.4

neo monitor system	**REF**	**Basic UDI-DI**
ES-820		++B195ES820V8

neo monitor (software)	**REF**	**Basic UDI-DI**
LE-800		++B195LE800UD

eego amplifier	**REF**	**Basic UDI-DI**
(product family)		++B195eegoamplifierZN
EE-411		++B195EE411RH
EE-511		++B195EE511RN

Mounting plate	**REF**	**Basic UDI-DI**
M02281		++B195M02281CS

All-In-One Computer	**REF**	**Basic UDI-DI**
OR-PC® 15		++B195M02334CN

waveguard EEG caps	**REF**	**Basic UDI-DI**
CA-420		++B195CA420PY
CA-421		++B195CA421Q2
CA-422		++B195CA422Q4
Adapters	**REF**	**Basic UDI-DI**
XC-810		++B195XC810Y6
XC-425		++B195XC425XX

Mobile cart	**REF**	**Basic UDI-DI**
vexio-cart plus 35E		4056634vexio-cartA3