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Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main, Germany
Identification number: 0535

European Representative: SAS Neuromed
Chemin du temple
84330 Le Barroux, France

Medical device(s):

1. Portable hearing screening device for ABR and OAE "Neuro-Audio-Screen"
2. Portable hearing screening device for OAE "Neuro-Audio-Screen/OAE"
3. Digital neurophysiological system for EP and OAE "Neuro-Audio"
4. Digital neurophysiological system for OAE "Neuro-Audio/OAE"
5. Digital neurophysiological system for EP "Neuro-Audio/ABR"

We herewith declare that the above-mentioned products meet the provisions of the Council Directives 93/42/EEC (MD) and 2011/65/EU (RoHS). All supporting documentation is retained under the premises of the manufacturer.

Device Classification: Class IIa (Rule 10), non-invasive, active device

Standards Applied: IEC 60601-1:2005
IEC 60601-1-2:2007

Decision according to Annex V, Section 3 of Council Directive 93/42/EEC concerning medical devices.

Certificate Number(s): CE577345

Start of CE-Marking: July 2008 (items 1, 2),
December 2004 (item 3),
March 2007 (items 4, 5)

Place and Date: Neurosoft Ltd, Ivanovo, Russia
November 19, 2013

Signature:



Aleksey Borisovich Shubin
President of Neurosoft Ltd