STATEMENT OF CONFORMITY

Ref.No. SE-1117291

Product:	Measuring device for patient with lesions in central nervous system
Tested by request of:	Aggero Medtech MT, Danderyds sjukhus SE-182 88 Stockholm Sweden
Manufacturer:	As above
Rating and principal characteristics:	100-240V~, 50/60Hz, 25-45VA, Class I, Type B
Trade mark (if any):	NeuroFlexor
Model/Type Ref:	NeuroFlexor
Additional information (if any):	See Appendix A
A sample of the product has been tested and found to be in conformity with:	IEC 60601-1:1988 and A1+ A2 EN 60601-1:1990 and A1 + A2
As shown in the Test Report (ref.no):	1117291-1

Stockholm

Date: 16 October 2012

Internal ref: JLA/MII/DAH

Intertek Semko AB

Medical Testing and Inspection

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Appendix A

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General product information and considerations:

NeuroFlexor is a medical technical device to be used for the measurement of neural and mechanical components contributing to increased passive movement resistance in patients with central nervous system lesions that develop spasticity.

The following applicable requirements have not been evaluated:

- Programmable electrical medical systems according to IEC/EN 60601-1-4
- Usability according to IEC/EN 60601-1-6
- Particular requirements for the Safety of Electromyographs and Evoked Response Equipment according to IEC/EN 60601-2-40
- Biocompatibility according to ISO 10993

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