Declaration

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Biocompatibility of AMBU Neuroline EMG Needle Electrodes

- Concentric Needle

D032

The Neuroline Concentric needle electrode has been tested for biocompatibility following requirements of ISO 10993 and G95-1, 1995 (FDA). The following tests were performed:

- In vitro cytoxicity assay (Elution Method), Scantox - November 2004.
- Intracutaneous (intradermal) reactivity test in the rabbit, Scantox - July 2004
- Test for delayed contact hypersensitivity using the guinea pig maximisation test, Scantox - September 2004
- Systemic injection in the mouse, Scantox - July 2004

All the tests were passed.

Rationale:

Since the type of stainless steel used for the Neuroline Subdermal and Twisted Pair Subdermal needles is the same as the Neuroline Concentric needle, the biocompatibility tests performed cover these two types of needles.

- Monopolar Needle

The Neuroline Monopolar needle electrode has been tested for biocompatibility following requirements of ISO 10993 and G95-1, 1995 (FDA). The following tests were performed:

- In vitro cytoxicity assay (Elution Method), NAMSA - 2004.
- ISO Intracutaneous Study in the rabbit, NAMSA - 2004
- ISO Maximization sensitization Study in the guinea pig, NAMSA - 2004
- USP and ISO Systemic injection in the mouse, NAMSA - 2004

All the tests were passed.

For and on behalf of Ambu A/S, Denmark

26 February 2006

Anne Bielefeldt, Regulatory Affairs Specialist