

Nemko Laboratory Authorization

Authorization: ELA 195-b

EMC Laboratory: ***Acme Testing Company
Post Office Box 3,
2002 Valley Highway,
Acme, Washington 98220
USA***

Scope of
Authorization: ***All Collateral Standards for electro-medical products,
EN 60601-1-2 (IEC 60601-1-2) and all IEC 60601-2-x as
listed below, with particular application to EMC
requirements only.***

Nemko has assessed the quality assurance system, the testing facilities, qualifications and testing practices of the relevant parts of the organization. The quality assurance system of the Laboratory has been validated against ISO/IEC 17025 or equivalent. The laboratory also fulfils the conditions described in Nemko Document NLA -10. During the visit by the Nemko representative it was found that the Laboratory is capable of performing tests within the Scope of the Authorisation.

Accordingly, Nemko will normally accept test reports from the laboratory as a basis for attesting conformity to these EMC Standards under the European Union Medical Device Directive (MDD 93/42/EEC) or the European Union Active Implantable Medical Device Directive (AIMD 90/385/EEC). When applicable, the test reports may be used to attest conformity to the national standards of other countries wherein Nemko has been authorized to attest conformity.

In order to maintain the Authorisation, the information given in the pertinent NLA-10 must be carefully followed. Nemko is to be promptly notified about any changes in the situation at the Laboratory, which may affect the basis for this Authorisation. The Authorisation may be withdrawn at any time if the conditions are no longer considered to be fulfilled.

The Authorization is valid through 31 December 2010.

Dallas, Texas, USA.

For and on behalf of Nemko AS:


T.B. Ketterling,

Nemko ELA Co-ordinator

Region: North America

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SCOPE OF AUTHORIZATION

BASIC TESTS AND ASSOCIATED STANDARDS

Capability to perform a basic test implies also that any product (family) standard calling up this basic test is also within the scope if mentioned below or not.

<i>Medical Device Standards</i>		
EN 60601-1-2:1993 EN 60601-1-2:1993 EN 60601-1-2:2001 + A1:2006 IEC 60601-1-2:2001 + A1:2006 EN 60601-1-2:2007 EN 60601-1-2:2007	EN 60601-2-1:1998 +A1:2002 cl. 36 EN 60601-1-2:1993	EN 60601-2-2:1993 cl. 36 EN 60601-1-2:1993 IEC 60601-2-2:2000 IEC 60601-2-2:2007 EN 60601-2-2:2007
EN 60601-2-3:1993 +A1:1998 cl.36 EN 60601-1-2:1993	EN 60601-2-5:2000 cl.36 EN 60601-1-2:1993	EN 60601-2-18:1996 +A1:2000 cl.36 EN 60601-1-2:1993
EN 60601-2-20:1996 cl.36 IEC 60601-1-2:1993	EN 60601-2-23:2000 cl.36 IEC 60601-1-2:1993	EN 60601-2-24:1998 cl.36 IEC 60601-1-2:1993
EN 60601-2-25:1995 +A1:1999 cl.36 EN 60601-1-2:1993	EN 60601-2-29:1999 cl.36 EN 60601-1-2:1993	EN 60601-2-30:2000 cl.36 EN 60601-1-2:1993
EN 60601-2-31:1995 +A1:1998 cl.36 EN 60601-1-2:1993	EN 60601-2-33:2002 + A1:2005 cl. 36 EN 60601-1-2:1993	EN 60601-2-34:2000 cl. 36 EN 60601-1-2:1993
EN 60601-2-35:1996 cl.36 EN 60601-1-2:1993	EN 60601-2-36:1997 cl.36 EN 60601-1-2:1993	EN 60601-2-38:1996 +A1:2000 cl.36 EN 60601-1-2:1993
EN 60601-2-40:1998 cl.36 EN 60601-1-2:1993	EN 60601-2-46:1998 cl.36 EN 60601-1-2:1993	BLANK

<i>Basic Standards</i>		
EN 61000-4-2:1995 +A1:1998 + A2:2000 IEC 61000-4-2:1995 +A1:1998 + A2:2000 EN 60801-1:1993 IEC 801.2:1991 IEC 801.2:1984	EN 61000-4-3:1996 + A1:1998 IEC 61000-4-3:1995 + A1:1998 EN 61000-4-3:2002 + A1:2002 IEC 61000-4-3:2002 + A1:2002 IEC 801.3:1984 ENV 50140:1993 ENV 50204:1995	EN 61000-4-4:1995, +A1:2002 +A2:2002 IEC 61000-4-4:1995, +A1:2000 +A2:2001 IEC 801.4:1990
EN 61000-4-5:1995 + A1:2001 IEC 61000-4-5:1995 + A1:2000 ENV 50142:1994	EN 61000-4-6:1996 + A1:2001 IEC 61000-4-6:1996 + A1:2000 ENV 50141:1993	EN 61000-4-8:1993 IEC 61000-4-8:1993 EN 61000-4-8:1994 + A1:2001 IEC 61000-4-8:1994 + A1:2001
EN 61000-4-11:1994 + A1:2000 IEC 61000-4-11:1994 + A1:2000	BLANK	BLANK

Dallas, Texas January 01, 2009.


 T.B. Ketterling, Nemko ELA Co-ordinator