



Progress Report Sept. 2009

LNE/G-MED: Sharing a Passion for Progress

LNE-GMED North America (LNE/G-MED) would like to provide you with periodic updates on the status of various regulatory and quality related issues. As a service to help you best determine your current and future certification needs, we provide you with the following updates:

Overview of Recent Guidelines Relative to the European Medical Device Directives

While the Medical Device industry is getting ready for the compliance to the revised requirements of the directive 2007/47/EEC revising the Medical Device Directives 93/42/EEC and 90/385/EEC, the other actors in the implementation of the regulation did not lose its time either, as the large number of guidance documents issued during the last 12 months witnesses.

1. Implementation of Directive 2007/47/EC – June 2009ⁱ

The main information from this guidance document was presented in our previous Newsletter from June 2009. It clarifies, among other points:

- The assessment activities the NB must perform to verify that the directive 2007/47/EC is actually taken into account by the manufacturers, including when the revision of the MDD reclassifies or suppose design changes of a medical device.
- How Declaration of Conformity should be issued during the transitory periods.
- The status of certificates issued prior to March 2009.

2. Borderline Products

2.1. Relation between the Medical Device Directives and the Machinery Directiveⁱⁱ – August 2009.

For devices that or both MD and machinery, this interpretative document confirms that only the assessment procedure from the MDD apply, although the manufacturer must also comply with any applicable essential health and safety requirement from the machinery directive which would not have an equivalent and as detailed ER in the MDD

2.2. Relation between the Medical Device Directives and the Personal Protective Equipment Directiveⁱⁱⁱ – August 2009.

The revision of this interpretative document concludes on the need to amend the article 1(6) of the MDD to clarify that a product, which is both a MD and a PPE, must meet both the ER and the Basic Health and Safety Requirements listed in the corresponding directives. These devices must be assessed according to both directives. It also clarifies the CE marking specificities when 2 NB are involved in these assessment activities and suggests that a NB for one directive can subcontract to another NB for the 2nd directive if it is not notified under both directives.

2.3. Medical Device-Drug Borderline products^{iv} – July 2009

The MEDDEV revision 3 was issued but revision 2 remains valid until March 2010, when the directive 2007/47/EEC takes effect. Its scope is extended to devices incorporating a human blood derivative. Note that some examples mentioned in the previous version have been removed and are now listed for further clarifications in the Manual on Borderline and Classification below.

2.4. *Manual on Borderline and Classification*^v – May 2009

This manual is updated on a regular basis to incorporate new consensus position on the status and the classification of specific borderline products between different regulations. New entries relates to Zinc oxide containing creams, eye drops with associated claims, products used in acute sore throat, plaster with capsaicin, bacterial/viral filters for patient undergoing pulmonary function testing, hydrocolloid plaster for blisters or movement monitor for babies.

3. Guidelines related to Clinical Evaluation

3.1. *Assessment of Clinical Investigation Notification by the Competent Authorities*^{vi} – Dec. 2008

This documents primarily applies to the CA to assist in their review process of a Clinical Investigation Notification. It details the elements the manufacturer must provide to the CA and the topics to address. It concerns especially the investigator brochure and the clinical investigation plan and associated forms (informed consent form, case report form, etc.), including the safety reporting. The annex of the document concerns specifically the devices incorporating a medicinal substance

3.2. *Clinical Evaluation on Coronary Stents*^{vii} – Dec. 2008

This annex to the MEDDEV on Evaluation of clinical data details the requirements for clinical evaluation, clinical investigation and post market clinical follow-up, depending on whether the device is Bare Metal Stent or a Drug Eluting Stent.

3.3. *Role of Notified Bodies in assessing Clinical Evaluation – MEDDEV DRAFT*^{viii}.

This project of annex to MEDDEV 2.7.1 details the method that the NB details the methods that the NB must follow while assessing:

- The clinical evaluation activities during their Quality System
- The clinical evaluation outcome, either by sampling the technical file during quality system audits relative to class IIa or IIb devices, or as part of the EC type/design examination per annex III or II.4 of the directives, respectively.

The document includes a detailed checklist to record the assessment in the latter case.

4. Rules relative to Notified Body and their Practices

4.1. *Change of Notified Body*^x – Nov. 2008

This essential document intends to assure that when a manufacturer decides to change of NB, any pending issue identified by the original NB will be taken into account by the new NB. This will prevent the temptation of switching when the NB assessments raise concerns the manufacturer tries to escape. At the same time, this supposes the NB to make necessary checks regarding the certification history of any new prospective customer.

4.2. *Certificates*^x – Nov. 2008

This document strictly applies to NB and details the information that must appear on each type of EC certificate, depending on the directive, the assessment procedure and the device classification. The main change introduced by the directive 2007/47/EC is the maximal validity of 5 years for all certificates except for the EC verification certificates or IVD batch release certificates

4.3. *Type/Design Examination and Report Content*^{xi} – Mar. 2009

If clarification was necessary, this guideline specifies the minimal information to be assessed as part of a type or design examination per Annex III or II.4 respectively. Note that the guidelines on review of class IIa or IIb as part of the Quality System certification per annex II.3, V or VI also refers to this document though.

4.4. Role of NB in the Vigilance System^{xii} – Mar. 2009

Interestingly enough, the regulation gives little responsibilities to the NB as part of the vigilance system. This document issued by the NBOG enhances the importance for the NB to be informed by the manufacturers of the patient issues they experience. This gives the means to evaluate the manufacturer's efforts to prevent their recurrence. The document also requests the NB to inform the CA whenever the NB and the manufacturer disagree on the reportability of a particular patient event.

4.5. Guideline for Competent Authorities to Define the Notification Scope of a NB^{xiii} – Mar. 2009

If this document primarily concerns the NB and their CA, it may have implications on the manufacturers too in term of information to provide to categorize the medical devices covered by the certification. Actually, this would harmonize the categories of devices for which each certification organization is designated as a NB. The manufacturers would therefore have to pick a NB for considered the category of device. The NB would also check that he has the appropriate scope of notification to address the manufacturer requests.

4.6. Technical Documentation Assessment on a Representative Basis^{xiv} – Jul. 2009

These long expected guidelines provides essential clarification on the sampling approach to apply for the Technical File review of Class IIa or IIb devices during the audits. It clarifies how to understand the definitions of "device subcategories" and "generic device group". The former corresponds more or less to the brad categories listed on the previous document in section 4.5. The latter correspond to the GMDN categories. The document also mentions the expected depth of the assessment and specifies that the review may require multiple experts to get involved and the review may be only partially performed on-site. Prior to extend the range of CE marked devices to a new device subcategory or generic device group, the technical file must be reviewed by the NB.

4.7. Reporting of Design Changes and Changes of the Quality System to the NB^{xv} – Jul. 2009

This new revision of the NB-MED recommendation provides additional clarification on the typology of design changes or changes of the quality system which must be notified to the NB. Still, each situation being unique, strict threshold between reportable and non-reportable changes appears difficult to establish and the guidance suggests that it should be supported by the manufacturer's procedure, audited by the NB, as applicable.

Abbreviations used in this Newsletter:

MD: Medical Device
 MDD: Medical Device Directive 93/42/EEC
 AIMD: Active Implantable Medical Device Directive 90/385/EC
 ER: Essential requirements from either MDD or AIMD
 NB: Notified Body
 MEDDEV: guidance document issued by the European Commission
 NB-MED: guidance document issued by the Notified Body Group.
 NBOG: Notified Body Operation Group
 GMDN: Global Medical Device Nomenclature.
 IVD: In Vitro diagnostic Medical Device



References

- ⁱ Manual on borderline and classification in the Community Regulatory framework for medical device, version 1.4: http://ec.europa.eu/enterprise/medical_devices/wg_minutes_member_lists/version1_4_manual072009.pdf
- ⁱⁱ Interpretation of the relation between the revised directive 90/384/EEC and 93/42/EEC concerning (active implantable) medical devices and directive 2006/42/EC on Machinery: http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_machinery_2009.pdf
- ⁱⁱⁱ Interpretation of the relation between the revised directive 93/42/EEC concerning medical devices and directive 89/686/EEC on Personal Protective Equipments: http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/interpretative_ppe_2009.pdf
- ^{iv} MEDDEV 2.1/3 rev.3 - Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative: http://ec.europa.eu/enterprise/medical_devices/meddev/meddev_2_1_3_rev_3_072009.pdf
- ^v Manual on borderline and classification in the Community Regulatory framework for medical device, version 1.4: http://ec.europa.eu/enterprise/medical_devices/wg_minutes_member_lists/version1_4_manual072009.pdf
- ^{vi} MEDDEV 2.7.1 – Guide for Competent Authorities in making an assessment of clinical investigation notification: http://ec.europa.eu/enterprise/medical_devices/meddev/guidelines2008.pdf
- ^{vii} MEDDEV 2.7.1 – Appendix 1: Clinical evaluation on coronary stents: http://ec.europa.eu/enterprise/medical_devices/meddev/ceff.pdf
- ^{viii} MEDDEV 2.7.1 – Appendix 2: Role of NBs in clinical evaluation: This draft document is not yet publicly available.
- ^{ix} NBOG BPG 2006-1 - Change of Notified Body: http://nbog.eu/resources/NBOG_BPG_2006_1.pdf
- ^x NBOG BPG 2006-2 - Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC - http://nbog.eu/resources/NBOG_BPG_2006_21.pdf
- ^{xi} NBOG BPG 2009-1 - Guidance on Design-Dossier Examination and Report Content: http://nbog.eu/resources/NBOG_BPG_2009_1.pdf
- ^{xii} NBOG BPG 2009-2 - Role of Notified Bodies in the Medical Device Vigilance System: http://nbog.eu/resources/NBOG_BPG_2009_2.pdf
- ^{xiii} NBOG BPG 2009-3 – Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment: http://nbog.eu/resources/NBOG_BPG_2009_3.pdf
- ^{xiv} NBOG BPG 2009-4 - Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis: http://nbog.eu/resources/NBOG_BPG_2009_4_EN.pdf
- ^{xv} NB-MED2-5-2Rec2 - Reporting of design changes and changes of the quality: http://www.team-nb.org/index.php?option=com_docman&task=doc_download&gid=1166&Itemid=38