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EUROMCONTACT Guidelines for SMEs to prepare for unannounced audits

Introduction

This document, drafted by Euromcontact, aims at providing guidance to manufacturers of Contact Lenses and Lens Care Products, on how to prepare for unannounced inspections from Notified Bodies. Following the PIP breast implant scandal, a series of measures have been put in place by the European Commission to strengthen controls on manufacturers of medical devices, including unannounced inspections. The future Regulation on Medical Devices will also include provisions for enforcing the unannounced inspections.

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1. Background

European medical device regulations are undergoing many significant changes that will impact manufacturers, suppliers, and Notified Bodies. Current Directives 90/385/EEC, 93/42/EEC and 98/79/EC allow to carry out unannounced audits but most of the Notified Bodies have not used this provision. One major change under the new regulation is the requirement for Notified Bodies to conduct unannounced audits on manufacturers of CE marked products.

2. Current situation

The Commission recommendation (2013/473/EU) regarding assessments and audits to be performed by Notified Bodies in the field of medical devices was published on 24th September 2013. The crucial point of this recommendation is the mandatory requirement of unannounced audits for all CE certified manufacturers at least once in every three years. This requirement does not differentiate between the size of the manufacturing operation, all types of manufacturers will get unannounced inspections.

3. EUROMCONTACT guidance for manufacturers

I. Action plan

Manufacturer should draw action plans for the implementation of unannounced audits and establish the relevant responsibilities in advance. Manufacturer should revise their internal processes to take account of unannounced audits.

II. Contracts with critical subcontractors and crucial suppliers

Commission Recommendation 2013/473/EU, Annex II, paragraph 2, states*:*
The quality system assessment should include audits on the premises of the manufacturer and, if this is also necessary to ensure efficient control, on those of its critical subcontractors or of its crucial suppliers. Notified bodies should establish a risk-based approach to identify such subcontractors and suppliers and should clearly document this decision process.

Commission Recommendation 2013/473/EU, Annex III, paragraph 2, states: *Notified bodies may, instead of or in addition to visiting the manufacturer, visit one of the premises of the manufacturer's critical subcontractors or crucial suppliers if this is likely to ensure more efficient control*.

A manufacturer should:

- Determine critical subcontractors and crucial suppliers *(to please refer to NBOG BPG 2010-1 and GHTF SG3/N17/2008 for more information)*;
- Verify selection criteria of critical subcontractors and crucial suppliers with their Notified Body;
- Amend their contracts with their critical subcontractors and crucial suppliers in order to allow the Notified Body to carry out unannounced audits, regardless of the length of the relationship between the manufacturer and the subcontractor;
- Find a new subcontractor and supplier in case of refusal of signing the contract;
- Take account if subcontractor or supplier needs to have a confidentiality agreement with Notified Body;
- Establish who bears the costs of the audit (manufacturer or subcontractor or supplier).

III. Frequency of unannounced audits

Commission Recommendation 2013/473/EU, Annex III, paragraph 1, states:
Notified bodies should carry out unannounced audits at least once every third year. Notified bodies should increase the frequency of unannounced audits if the devices bear a high risk, if the devices of the type in question are frequently non-compliant or if specific information provides reasons to suspect non-conformities of the devices or of their manufacturer.

A manufacturer should:

- Update the contract with the Notified Body to include unannounced inspections including the cost associated;
- Consult with their Notified Body in order to establish clear rules of determining of frequency of unannounced audit.

IV. Presence of personnel responsible for crucial processes and maintaining of quality system

A manufacturer should:

- Establish that key managers and employees that are required for the unannounced audit should be present or should be contactable or accessible in short notice;

- Consider establishing deputies or representatives for important roles required for the unannounced audit or agree with the Notified Body on contact modalities if no deputies are available (for example single Person Company).

VI. The quality management system and the technical documentation

Commission Recommendation 2013/473/EU, Annex II states:
In the case of full quality assurance system, the verification should ascertain that the application of the quality system assures the conformity of the devices with the legal requirements set out in Directive 93/42/EEC. In the case of production or product quality assurance, the verification should ascertain that the application of the quality system ensures the conformity of the devices with the device type.

Commission Recommendation 2013/473/EU, Annex II states:
Notified bodies should verify the manufacturer's procedures with regard to the product documentation. The procedures relating to the product documentation should ensure that all products intended to be placed on the market or put into service are covered by the necessary certificates issued or to be issued by the notified body.

A manufacturer should:

- Have the quality management system documentation and the technical documentation in place when the unannounced audit team is present at their premises.

The most important issues examined by the NB:

- qualification of a medical device;
- classification of a medical device;
- medical device compliance with the relevant Essential Requirements;
- risk management;
- compliance the declaration of conformity and the technical documentation with medical devices that are assessed;
- clinical evaluation;
- post-market clinical follow-up;
- assurance of compliance of the medical devices by the quality system;
- procedures regarding the design and product development, including control of change procedures;
- work instructions on the required processes;
- traceability;
- vigilance data;
- Manufacturer's business organization including the control over the manufacturer's subcontractors.

VII. Production plans

Commission Recommendation 2013/473/EU, Annex III, paragraph 3, states: *Within the context of such unannounced audits, the notified bodies should check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conformity with the technical documentation and with legal requirements*.

A manufacturer should:

- Establish with Notified Body information about production plans especially in case of periodic production.

VIII. Contract with Notified Body

Contract should include:

- Provisions allowing NB to perform unannounced audits, as well as standing invitation letters so that auditors can receive visas to audit different premises if needed for example when critical subcontractors or suppliers are located in countries that require visa;
- Cost associated with unannounced inspections;
- Determine communication about production plans;
- Establish the way of verifying and authenticating the auditors when they show up for an unannounced audit (e. g. an authentication letter is handed to the manufacturer by the audit team).

IX Sampling criteria and testing procedure

Commission Recommendation 2013/473/EU, Annex III, paragraph 4, states: *These samples should be tested by the notified bodies or by qualified personnel under their observation on their own premises, or on the manufacturer's premises, or on the premises of the manufacturer's critical subcontractor or crucial supplier or in external laboratories. Sampling criteria and testing procedures should be defined in advance.*

Manufacturer should:

- Establish with the Notified Body sampling criteria and testing procedure;
- Establish a list of external laboratories where samples will be tested;
- Establish test that can happen at the manufacturer and test to be done externally.

X. Budget

Manufacturer should:

- Establish budget for the new cost associated with an unannounced audit and sample testing.

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