Information about unannounced audits performed by Notified Body

Applicable for manufacturers holding a valid CE-certificate according to the 93/42/EEC Medical Device Directive.

An unannounced audit is an audit of a manufacturer or a significant critical subcontractor (e.g. outsourced design, manufacturing, sterilisation) or a crucial supplier (e.g. component, raw material) where the manufacturers are not informed prior to the audit. The unannounced audits are product focused audits. All audited elements are geared towards the sampled device(s). Usually the scope of the audit is to verify that manufactured devices (on the day of the audit) are in compliance with the technical file. However, the audit scope depends on the reason for selecting the company.

A statement is to be presented to the manufacturer subject to the unannounced audit, which states that Notified Body's management has decided that an unannounced audit of the company shall be carried out. The purpose of an unannounced audit is to collect evidence in order to document compliance or lack of compliance in relation to the audit scope. The statement shall be signed by Notified Body's management.

The duration of an unannounced audit is, as a rule, minimum one man day and executed by at least two auditors on site. Time for preparation and follow-up of at least on man day will be needed in addition.

This audit shall be without any warning and shall be totally unexpected.

Manufacturers must have appropriate contracts with their subcontractors that allow an unannounced visit by their Notified Body.

Table 1: Expectations for the frequency of unannounced audit

Minimum frequency in number of years for an unannounced visit	**Classification**			
	Is/Im	**IIa**	**IIb**	**III**
Normal conditions	3 yr	3 yr	3 yr	2 yrs
If the device bears high risk	2 yr	2 yr	1 yr	1 yr
Devices that are often non-compliant	2 yr	2 yr	1 yr	1 yr
Specific reasons for suspicion	2 yr	2 yr	1 yr	1 yr

References:

93/42/EEC Medical Device Directive section 5.4

Commission recommandation 2013/473/EU: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF

Code of Conduct by TEAM- NB

Certification agreement

CE certificate