Frequently Asked Questions

Unannounced audits for manufacturers of CE-marked medical devices

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Note: Answers given in this document are based on the current GMED interpretation and practices at the date of publication of the document. This information may change in the future.

	Theme	Question	Answer
1	Regulations	What is an unannounced audit?	Unannounced audits are additional audits for which Notified Bodies (NBs) do not announce the date to manufacturers. This means the auditors commissioned by the notified body will arrive on the sites to be audited and proceed to the audit without giving the manufacturer prior notice. These audits are carried out randomly at least once every 5 years and are in addition to the audits scheduled as part of the surveillance. They may take place on the premises of the manufacturer, of subcontractors, or of suppliers.
2	Regulations	Are unannounced audits part of a new requirement?	No, the possibility for a NB to conduct unannounced audits was provided for by the three European directives on medical devices (90/385/EEC, 93/42/EEC, 98/79/EC), associated with the Recommendation of the European Commission of 24 September 2013. Since the implementation of CE marking procedures, unannounced audits have been carried out by all NBs.
3	Regulations	Where can I find the requirements for unannounced audits?	Regulations (EU) 2017/745 and 2017/746 set out the arrangements for conducting unannounced audits in Annex IX Chapter I, paragraph 3.4 and Annex XI Part A, paragraph 7 (which refers to paragraph 3.4 of Annex IX Chapter I).
4	Regulations	Why does GMED perform unannounced audits?	As a NB, GMED follows the requirements of the Regulations (EU) 2017/745 and EU 2017/746 regulations applicable to it.
5	Contract	Does my current contract contain a clause regarding unannounced audits?	Yes. GMED has included in the contracts established under a directive or an EU Regulation, the provisions related to the performance of unannounced audits.
6	Schedule	When will unannounced audits start?	Unannounced audits under a directive are already performed. Unannounced audits under an EU regulation will be performed after obtaining an EC certificate according to the applicable regulation.
7	Methodology	What are the trigger criteria for an unannounced audit?	In accordance with current regulations, unannounced audits are carried out during the NB's surveillance activities. Nevertheless, their frequency may be intensified if the devices present a high risk, if there are findings of non-compliance or if certain information leads to the suspicion of non-compliance in the devices or in their manufacturer.
8	Methodology	Do companies receive prior notice (very short notice) for an unannounced audit?	In accordance with the regulations, unannounced audits are carried out without informing the company in advance. The audit teams will visit your premises, your subcontractors or your suppliers **without any prior notice**. These audits can take place at any time (night and day depending on your activity). As from now, the manufacturer must implement the provisions needed (on his premises and on his subcontractors/suppliers premises) to be able to host our teams and let them conduct the audit in satisfactory conditions.
9	Scope of application	Do unannounced audits apply to all MDs?	Yes. Unannounced audits apply to all types of CE marked DMs, regardless of the method of proof chosen by the manufacturer. However, this requirement does not apply to DMs that do not require NB intervention for certification (self-certified devices).

10	Methodology	How often are audits performed for manufacturers who produce MDs of different classes (Classes IIa, IIb and III, B, C or D)?	The frequency of audits is determined by conformity assessment findings and data from surveillance activities including vigilance data, complaints, PMS and not by device class. All devices are concerned by unannounced audits. Based on the data collected, GMED determines the objective of the unannounced audit and the devices concerned. Depending on the findings, one or more unannounced audits may be carried out in 5 years.
11	Methodology	Is there one unannounced audit per certificate issued, or one audit per legal manufacturer?	The unannounced audit program is established by legal manufacturer. It is defined by taking into account the results of the quality management system and conformity assessment of the devices covered by the CE marking and all available data from surveillance including vigilance data, complaints, PMS etc...). An unannounced audit can be performed at your subcontractors or suppliers.
12	Methodology	How long does an unannounced audit last, and how many auditors are commissioned?	The duration of the unannounced audit and the number of people assigned to carry out the unannounced audit are determined according to the objectives of the audit, the number of devices and processes to be examined and the skills required. The minimum duration of an audit is one day. The audit can be performed by a single auditor or by a team of auditors. Our auditors can be accompanied by experts
13	Methodology	Will the auditors be GMED auditors or external auditors?	Auditors who may be involved in unannounced audits may be GMED staff auditors or auditors assigned by GMED. Auditors performing audits for GMED are qualified auditors under the same provisions.
14	Methodology	Are the auditors who perform the unannounced audits the same as those who perform the certification cycle audits?	GMED selects the auditors to perform the audits. This is done taking into account the necessary skills and the objectives of the audit. Depending on the case, it may be the same auditors as those involved in the certification cycle or a different team of experts
15	Definition	How do you know if a subcontractor or supplier can be selected during unannounced audits?	The objective of the unannounced audit is to verify the continued conformity of the products and the respect of the applicable regulatory requirements. Any subcontractor or supplier involved in the realization of the product and/or in activities related to the conformity of the product may be included in the unannounced audit program.
16	Definition	Under what form must the manufacturer describe his subcontractors and suppliers?	The manufacturer shall provide the NB with a list of essential subcontractors and suppliers as required by GMED when preparing for audits (initial and surveillance). This list is reviewed prior to the audits and is subject to verification during the planned audits of the certification cycle.
17	Contract	What happens if the manufacturer, the subcontractor or the supplier refuses the unannounced audit?	In case the manufacturer, his subcontractor(s) and/or supplier(s) refuses to welcome the audit team, the contract between GMED and the manufacturer may be breached, resulting in a suspension, or even the withdrawal of certificates. The manufacturer is charged for the travel expenses and the costs incurred for immobilizing the teams.

18	Contract	How much does an unannounced audit cost?	The costs associated with an unannounced audit will be calculated in the same manner as cycle audits. A budget estimate is provided in the client's cycle estimate (page 3 of the estimates). This estimate does not include testing costs. This cost depends on several parameters: - The number of days the audit lasts (at least one) - The number of auditors - The place where the audit takes place (travel expenses) - Administrative and report fees - Performed tests and associated costs if samples* are taken - Expenses pertaining to tests* - Safety measures of the auditors As for tests, if they must be performed in a laboratory outside the manufacturer's premises, a quote will be sent according to the elements received by the laboratory performing the tests. The quote must be approved and paid for before tests are performed. The maintenance of the certificate(s) held by the manufacturer depends on the tests performed and their results. ** In accordance with GMED's General terms of sale and provision of services (point 6) "All testing-related costs are the responsibility of the Customer, and/or its suppliers and subcontractors. […] In the event of purchase by GMED of samples to perform the tests, the Customer undertakes to reimburse GMED upon submission of the related invoice, including on behalf of its suppliers and/or subcontractors. Any sample shipping or reshipping costs (including customs duties, insurance, packaging costs) remain the responsibility of the Customer and/or its suppliers and/or subcontractors.**
19	Contract	Who is charged for the unannounced audits? Can I refuse to pay?	The costs associated with unannounced audits are paid for by the manufacturer, including the audits performed on the premises of its subcontractors/suppliers. In case the manufacturer refuses to pay, the contract between GMED and the manufacturer may potentially be breached, resulting in a suspension, or even the withdrawal of certificates. Once the unannounced audit has been performed, the manufacturer receives an invoice detailing the costs associated.
20	Contract	What is the impact of unannounced audits on subcontractors or suppliers?	As the manufacturer is responsible for the safety and performance of its products, the impact of non-conformities found during the audit of its subcontractors or suppliers is its responsibility. The manufacturer is therefore responsible for defining and conducting the necessary actions to resolve the non-conformities.
21	Regulations	If subcontractors or suppliers are ISO 13485 certified, are they subject to unannounced audits?	Certification to ISO 13485 of a supplier or subcontractor is one of the criteria taken into account by the NB when establishing the unannounced audit programme. Given the objectives of unannounced audits as defined in the regulations, any subcontractor or supplier may be subject to an unannounced audit.

22	Preparation	How can I prepare for an unannounced audit?	The manufacturer shall define and establish the necessary provisions to allow GMED to carry out any unannounced audit, under normal conditions of reception and safety of the auditors. The manufacturer shall ensure that all documents that may be required during the audit can be made available and that the sites and infrastructures are accessible. The methods of substitution and delegation useful for the good execution of the unannounced audit must be defined and described within the quality management system of the company, suppliers and subcontractors. In order to prevent any problems, the manufacturer may define contractual provisions with its subcontractors or suppliers, in order to allow unannounced audits to be carried out by GMED on their site.
23	Preparation	What elements must the manufacturer make available to GMED?	The manufacturer must provide the following elements proposed by GMED for unannounced audits to be performed: - Timeframe of any absence of production - The list of his subcontractors and suppliers - Periods when sites are shut down (whether the premises of the manufacturer, of his subcontractors or of his suppliers) - The open invitation letters (required to obtain a visa for performing unannounced audits) for his various sites and those of his subcontractors or suppliers
24	Preparation	What format should the manufacturer use to send its information?	The information is to be transmitted every 12 months and as soon as updated (including updates concerning the periods of manufacture/closure of the sites).
25	Preparation	For manufacturing on demand, how should the manufacturer send the dates when there will be no manufacturing?	If it's easier to communicate the manufacturing periods, the manufacturing periods can be sent.
26	Preparation	Will GMED give examples of the invitation letter for the visa?	A model open invitation letter is included in Annex of contracts for CE marking certification.
27	Preparation	If we are a subcontractor, to whom should we send the manufacturing schedule?	The schedule (including those of the subcontractor and suppliers) are sent to the legal manufacturer, who sends the information to GMED.
28	Methodology	What happens if the "key" staff members are not available on the day of the audit?	When signing the certification contract, the manufacturer undertakes to implement the provisions needed to provide answers to the auditors' questions. This means he must define procedures regarding temporary replacements and delegations required for the unannounced audit to be performed in satisfactory conditions. By signing the contract, the manufacturer also commits to ensuring his subcontractors and suppliers make similar provisions. Any refusal from the staff to cooperate, preventing the audit to be performed in satisfactory conditions, may hinder the maintenance of the certificates (suspension or even withdrawal).

29	Methodology	As a subcontractor/supplier for numerous manufacturers certified by GMED, can a grouped unannounced audit be considered?	The scope of unannounced audits is related to the MDs covered by the certificates issued to the manufacturer. This provision remains valid if the unannounced audit takes place on the premises of a subcontractor or a supplier. The activity of subcontractors/suppliers will be audited to be verified as a whole, and in that sense they may be subject to an audit that would be valid for several manufacturers. The choice to carry out a grouped audit is determined by GMED.
30	Methodology	Are there recognition procedures for unannounced audits between notified bodies?	Today, there are no recognition procedures for unannounced audits between notified bodies.
31	Methodology	Does being both a manufacturer in the sense of an EU regulation, a directive and a subcontractor increase the possible frequency?	Yes. A company who is both a manufacturer and a subcontract would be subject to two unannounced audits according to its two activities.
32	Methodology	In which language will the unannounced audit be conducted?	GMED conducts audits in English and French, depending on the client. The unannounced audit will be in one of these two languages except in particular cases. If necessary, there will be an interpreter.
33	Methodology	What are the provisions for unannounced audits that are performed in foreign countries, like China?	In such case, the audit team would be constituted of auditors and interpreters.
34	Methodology	What happens if an audit by another NB or an inspection by a regulatory authority is already being performed on the day of the GMED unannounced audit?	GMED is aware this situation might occur and prove quite complex to deal with. In such a case, the feasibility will be assessed on site depending how the joint exercises are performed. The arguments presented by the company for the possible non-feasibility of the unannounced audit will appear in the unannounced audit report. In addition, the manufacturer will be charged for the travel expenses and costs incurred for the audit, regardless if it takes place whether the audit is performed or not.
35	Methodology	How is an unannounced audit conducted?	As the unannounced audit is not planned and communicated to the manufacturer, the audit plan is not communicated prior to the audit. When the audit team arrives on site, it presents to the attention of the manufacturer, a mission letter relating to the unannounced audit. The audit is then conducted according to the usual methods of carrying out an audit. An opening meeting is held at the beginning of the audit to present the audit objectives and the associated plan. A closing meeting is also held to review the audit and to present any non-conformities to the company. If the unannounced audit includes the collection of samples for testing by a laboratory, the samples will be identified during the audit. The transportation of the samples to the test site remains the responsibility of the manufacturer.

36	Methodology	What are the output data of the unannounced audit?	At the end of the audit, the auditors make an oral report during the closing meeting of the audit. A written report will be given to the manufacturer, respecting the usual deadline of the certification cycle. Depending on the nature of the non-conformities found and the corresponding risks, the timeframe for processing will be adapted. As for the audits of the certification cycle, action plans in response to non-conformities are expected.
37	Methodology	What happens in the event of a major non-compliance?	Once the unannounced audit has been performed, and the report issued, the usual communication process with the NB is implemented, including what regards majeures non-conformities. Then the NB makes a decision according to the result of the unannounced audit, and assesses its influence on the audit programme and on the maintenance of the certification.
38	Methodology	What is audited?	An unannounced audit is a surveillance activity carried out by the NB to verify that the manufacturer continues to meet the regulatory requirements, after obtaining one or more certificates. Unannounced audits are conducted at the manufacturer and, as appropriate, at subcontractors and suppliers. The scope of unannounced audits will include all DM covered by CE marking certificates issued by the NB, regardless of the class and conformity assessment applied. The unannounced audit is an audit in which a traceability exercise is performed, focusing on one or more selected devices. These devices can be finished devices from a recent production or in-process products, selected on the production line. The exercise of traceability will relate to the whole of the processes of manufacture, from the arrival of the raw materials and components until the release of the device, finished product. The traceability exercise will be conducted in order to verify the compliance of the practices with the technical documentation and legal requirements. Tests on samples of medical devices or products from the manufacturing process will be performed to verify the conformity of the selected device to the technical documentation. The test is performed either on site with the manufacturer's resources or by an external laboratory.
39	Methodology Tests	Can the audit team take samples with a view to perform these tests?	In accordance with regulatory requirements, during unannounced audits, tests on product samples must be performed to verify compliance with the technical documentation. These tests can be carried out on finished products or on sample products. These tests can be performed during the audit at the manufacturer's site or be taken to an external laboratory. The NB may also take samples of medical devices from the market for testing and verification of compliance of the medical device.
40	Methodology Tests	Can the manufacturer refuse the testing lab that GMED proposed and propose another?	GMED as a notified body selects and qualifies testing laboratories according to different criteria to ensure the quality of testing. GMED includes price in the selection criteria to ensure fairness among the laboratories. The manufacturer may refuse the laboratory proposed by GMED but shall propose a laboratory independent of the manufacturer and meeting GMED criteria. The protocol and test conditions cannot be decided or modified by the manufacturer.
41	Methodology Tests	In case products are taken, how are quantities determined, and where are samples taken: on the premises of the manufacturer, on the premises of the supplier, or from the market?	The quantities of samples taken depend on the tests to be performed and the range of products covered by the certificates

42	Methodology Tests	What are the criteria that GMED will use to determine if the device will be tested by the manufacturer or another laboratory?	The location of the test is determined by taking into account the purpose of the test, the manufacturer's infrastructure to perform the test or not, the necessary test conditions and the need to perform the test by an accredited laboratory.
43	Methodology Tests	Which tests may GMED choose to perform on the MDs/components?	The tests to be performed is determined by taking into account different parameters such as the results of the conformity assessments performed, the tests performed by the company and the results obtained, mechanical, chemical, physical/chemical, electrical safety, EMC, biocompatibility tests, etc.
44	Methodology Tests	How does GMED manage sample taking from an accounting/financial point of view, in particular for rather costly MDs or components?	These provisions are already provided for in the current GMED Terms and Conditions, since the manufacturer must ensure all the required conditions for GMED to be able to perform the unannounced audit in satisfactory conditions.
45	Methodology Tests	What happens if the results of the tests on the medical device are different than the results given by the manufacturer?	GMED analyses the results in order to identify causes and may request some information to the manufacturer in view of this analysis. The analysis takes into account elements relating to the safety of the device to the patient/user/environment and the performances indicated by the manufacturer. GMED evaluates the impact of the results of this analysis on the certification.
46	Regulations	In case some products are taken to perform the tests, and entrusted to third party laboratories, what are the provisions implemented by GMED to manage conflicts of interest and ensure confidentiality? Are the name of the laboratory in charge of the tests and the testing methods selected issued to the company?	GMED will take care of identifying the laboratories which have no conflict of interest for the mission to be accomplished, and will ensure the confidentiality of the data is respected as part of the general provisions in force. The name of the laboratory may be given to the manufacturer; however, GMED remains the only intermediary and implements provisions to ensure confidentiality and impartiality are respected.
47	Methodology	If the unannounced audit takes place on the premises of a critical subcontractor or a crucial supplier, who will receive the audit report, including any non-conformity, if applicable?	Since the certification contract is established between GMED and the manufacturer to whom CE marking certificates are attributed, the unannounced audit report is sent to the manufacturer. The critical subcontractor or the crucial supplier will have been orally informed of the results at the end of the audit. It is the responsibility of the manufacturer to search for causes and to implement remedial and corrective actions.
48	Methodology	How does the unannounced audit fit into the certification cycle? Do you review the previous or on-going non-conformities?	Since unannounced audits are conducted outside the normal surveillance programme and is performed in parallel or in addition, the GMED audit team does not carry out any follow-up of the previous/ongoing non-conformities. Nevertheless, when preparing and performing the unannounced audit, our auditors take into account the cycle audit history. If non-conformities arise from the unannounced audit, they will be addressed during the unannounced audit and followed up during the cycle audits.

49	Methodology	Does GMED notify the manufacturer when the unannounced audit is scheduled on the premises of a critical subcontractor or a crucial supplier?	No. GMED does not notify the manufacturer of an audit planned on the premises of one of his subcontractors or suppliers. However, the subcontractor/supplier may warn the manufacturer GMED is present on his premises to perform an unannounced audit.

For any further information, please do not hesitate to contact us to the following email addresses: info@lne-gmed.com or gmedna@lne-gmed.com