

Medical Devices : Guide to defining a test strategy



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This guide is a document intended to support medical device manufacturers/importers as they plan the preclinical technical assessment of their devices.

Using an incomplete list of questions, the approach suggested here is used to draw up a strategy regarding the tests needed for technical assessment of a medical device.

Defining a test strategy is a procedure conducted with the laboratory responsible for carrying out the tests. The laboratory's expertise and experience will allow you to structure your plan with the right questions.

► Why define a test strategy ?

• To control and reduce the costs of tests

Poor prior planning can result in increasing the number of tests, in later re-evaluating an initially-forgotten option/variant, or in resubmitting the device to an unknown laboratory to demonstrate its compliance with an unknown foreign standard deviation. The tests may involve specific and uncommon human and technical resources. In certain cases, the cost of a test campaign may therefore be quite substantial.

• To control the test period and offer protection against a delay in placing the device on the market

For some medical devices, standardised test protocols specify fatigue cycles over periods that cannot be shortened or test programmes that may require several samples.

Thinking carefully about the choice and number of samples submitted for testing therefore avoids extending the test period. Similarly, thoroughly preparing a technical file (drawings, wiring diagrams, definition of 'worst cases', details of components, etc.) reduces the number of exchanges between the laboratory and the manufacturer during the test period

• To take full account of standards applicable to your product in the targeted countries

Additional requirements or partial modifications may be applied to an international technical standard, when it is approximated into the regulations of certain countries. These differences, called 'deviations of standards' can make it difficult to identify the tree structure of standards applicable to a medical device. Defining a test strategy must therefore lead to correctly identifying the standards that are applied to the product. applicable in the countries in question.

• To anticipate the evaluation of material changes / future variants of the device

A correctly constructed test strategy should allow the foreseeable material developments or

options for a piece of equipment to be considered while also limiting the number of additional repeat tests. In this way, defining a 'core' test programme leaves the way clear to add and evaluate options later, without the need to restart all the tests described in a standard.

- **To identify success factors for exporting your medical device in advance**

Drawing up a test strategy should lead the manufacturer to ask itself a number of questions essential for sound international recognition of the test results. The choice of internal and external laboratory, the type of accreditation, the content of test reports and final presentation of the results are all aspects that may or may not facilitate the recognition of tests conducted by foreign organisations.

▶ **Defining your test strategy in a minimum of 6 points**

A test strategy is generally included in a more general certification plan. The strategy may vary in complexity depending on the technologies found in a medical device or international target markets. It would therefore be simplistic to believe in a single possible recipe to define a good strategy. However, we suggest at least basing the plan on 6 essential points:

- Identify the target country(-ies) to sell your Medical Device and the applicable standards
- Define the date for placing it on the market and identify the versions of standards to be used
- Consider the developments of an MD
- Identify the laboratory(-ies) to which the tests are to be contracted
- Anticipate the sequence of tests
- Present the test results and conclusions

▶ **Identify the target country(-ies) to sell your Medical Device and applicable standards**

Listing the target countries for sale of your medical device makes it possible to identify the applicable national regulations. These Regulations (European Directives, FDA regulations in USA, SCC Regulations in Canada, etc.) make it subsequently possible to identify the applicable standards recognised in the relevant countries. Although it is rarely mandatory to apply a standard, it remains a consensual tool to demonstrate the compliance of a device with regulatory requirements.

Evaluating the compliance of a medical device may require the application of several times. The useful standards structure is therefore based on one of a few general standards that can refer to other 'collateral' standards or 'product' standards for technical aspects specific to the device in question.

- **Have I properly considered all standards applicable to my device ?**

The challenge is to ensure that the applicable standards structure is as complete as possible compared to existing best practice. If in doubt, it is recommended to be supported by your test laboratory, whose expertise will provide useful additional information.

As an example, an electric medical bed will be assessed according to international standard IEC 60601-1 (general safety standard for medical electrical devices). The requirements of this standard will be supplemented by 'product' standards specific to electric medical beds: standard IEC 60601-2-52 and standard IEC 60601-1.1, if the bed is designed to be used at the patient's home. In conjunction with these three standards, electromagnetic compatibility will be assessed according to 'collateral' standard IEC 60601-1-2 (requirements for electromagnetic compatibility of medical electric devices).

The content of these standards may cite other specific test standards such as standard IEC 60529, which specifies the protocol for testing resistance to water penetration in electrical equipment.

Standards recognised as a tool for evaluating the requirements of a national regulation are generally included in published lists, regularly updated by the competent national authorities. In some cases these lists can be viewed online, such as the list of harmonised European Union standards, the list of standards recognised by the FDA for the USA or the list of standards recognised by SCC in Canada.

'Collateral' standards, called in the contents of a general standard, are easily identified by consulting the chapter 'Normative references', found at the beginning of each normative document.

- **Have I properly considered any normative amendments that may exist ?**

A standard is a document that can undergo changes in its content over time. Corrections, details, modifications or additions may therefore constitute amendments or corrigendum to the normative reference framework. These amendments have the same normative status as the original text and must be applied in conjunction with it, insofar as the amendment will be cited in a list of standards recognised by a competent national authority.

- **Have I properly considered foreign normative deviations that may exist ?**

An international standard may sometimes be transposed at national level with partial adaptations or modifications of the content to the country in question. The reasons for these differences are most frequently technical, e.g. a difference in voltage between the Japanese and European electrical supply. It is therefore necessary to keep a record of them from the beginning. A foreign normative deviation that might have been forgotten when carrying out tests according to the international reference standard may subsequently require a significant number of tests to be repeated. Conversely, normative deviations considered at the same time as evaluating the device according to the international reference standard make it possible to combine laboratory procedures and optimise costs and completion times.

- **Do I need product certification to ensure the sale of my device ?**

Depending on the target markets, evaluation of compliance with one or more standards may not be sufficient. For example, obtaining NRTL marks (National Recognized Testing Laboratories) may be an essential regulatory condition for selling an electric medical device in the United States. Similarly, obtaining a voluntary mark in France, such as the 'NF medical' for condoms, may prove to be a vital differentiating factor compared to competitive products. Finally a CB certification (Certification Body) may facilitate recognition of test reports and the export of an In Vitro Diagnostic machine in Asia.

In general, certification reference frameworks include technical requirements taken from standards and add specific requirements to them (factory audit/inspection, special sampling, periodic partial tests, etc.). Whether voluntary or a regulatory requirement, product certification can present varied and miscellaneous rules. It therefore remains an aspect that must be considered before the test phase.

- **Are there special technical aspects to be satisfied if the medical device is to be paid for by social security or health insurance ?**

Compliance to a standard may influence placing a device on the market but not necessarily its reimbursement by social security or health insurance. For example, anti-bedsore mattresses, wheelchairs or prosthetic feet for amputees, which are covered by special technical specifications in France. The reimbursement of these devices, with special technical features, is influenced by compliance with national, non-normative protocols.

In such cases, it is beneficial to plan carrying out tests in parallel according to existing technical standards and special national technical specifications. Furthermore, it is not uncommon for national technical specifications on the reimbursement of MDs to take account of requirements described in standards applicable to placing the device on the market. Savings in time and money can be achieved if the test laboratory combines part of the protocols.

- **What should I do if my medical device is not covered by any standard or if certain functions/performance are not covered by any existing standard ?**

Standardisation is a process generally meeting the need to standardise mature technologies. In this context, innovations, frequent in the field of healthcare equipment, may come up against a lack of appropriate normative reference frameworks.

However, this does not mean that the device manufacturer is exempt from any approach to evaluate the compliance of its product with applicable regulatory requirements. Analysing the risks of its device should lead it to drawing up a specific protocol by asking itself certain questions, such as :

- What performance do I want to ensure?
- What risks should I control?
- How can I adapt an existing test protocol for another device to the similar features of mine?
- Can a laboratory specialised in carrying out protocols help me?

► Define the date for placing it on the market and thus deduce the correct versions of standards to be used

This question should lead to consideration of two fundamental aspects:

- **Provide enough time for technical evaluation, carrying out tests and resolving non-conformances**

Tests are useful tool to improve reliability of the design of a medical device and to control the risks associated with its use. In this sense, qualification/certification tests should not be considered as the last step for putting a device on the market. Unsatisfactory results would then lead to late modification of the design and a damaging delay to marketing the device. Tests are interim validation steps in the design cycle of a medical device. Complete final qualification is the last step in consolidating the demonstration of compliance with regulatory and normative requirements.

- **Use the correctly dated versions of standards recognised in the target countries**

The publication of a new standard or an amendment does not lead to its immediate harmonisation or regulatory recognition in all countries. In certain cases, to put a device on the market quickly, the earlier and still-current version must be selected. The approximation of an international standard (ISO or CEI) into a harmonised European standard may take one or more years.

Similarly, a standard never becomes obsolete as soon as its new version is published. There is always a period where the old and new versions stand side by side, thus providing a transition and overlapping validity covering several years.

The recognition or harmonisation date for a version of a standard in a country is therefore a key factor to be correlated with the planned date for putting the device on the market.

Furthermore, an active normative watch makes it possible to anticipate foreseeable changes in recognition or harmonisation. For example, a draft standard at the end of the drafting process or recent publication of a new international standard (ISO or CEI) that may not yet be recognised remains anticipation to be considered when planning to put a device on the market in the medium term. In particular, this may avoid having to repeat a compliance evaluation several months or years later.

► Consider material developments to your medical device

• My device is a development of existing equipment tested in the past

In such cases, partially repeating tests, limited to certain requirements, may prove adequate, depending on the nature of the changes. It is advisable first to ensure that the standard(s) used in the past is(are) still in force.

Then identify the articles of the standard affected by the changes. This approach is not always simple to carry out in itself because articles in the standard may be linked to each other. The same applies to links with other collateral or supplementary standards, applicable to your device. Test authorities or certification bodies may ask for an argument to be constructed to justify the choice of articles selected for partial tests. A specialised and experienced laboratory can support the company in this process.

Finally, if partial testing is preferred, it is important to assemble all the evidence adequate to demonstrate full compliance with the standard based on an old test report. This means correctly identifying the device tested in the old report, consistent with the identification of the new device. The test conditions and parameters must also be known and consistent with those used for the new evaluation.

It is appropriate to question the validity and possible recognition of the old test report that the laboratory will use to conduct the partial tests and to issue a new overall opinion on compliance. A report issued under accreditation may therefore be as criterion requested by your laboratory to take the old results and include them in its new report.

• My device is available in a range of products having a common core

A first strategy that may be adopted is a complete set of tests applied to the base version and partial tests conducted on the variants.

As stated above, the partial test programme will be based on the identification of articles affected by the variants. Caution: in certain cases of product certification that are based on 'type' tests, each variant must be covered by full tests in order to be certified.

A possible alternative to this first approach is to identify 'the worst case', evaluation of which will validate an entire range. Identification of the worst case must be based on factors such as examination of current best practice, a literature review, calculations, computer simulations, modelling, reduced pre-tests, etc.

• My device has been tested according to an old standard that has just changed

Comparative analysis between the old and the new versions is used to identify the articles in the standard that have been modified or added and that could lead to repeating some of the tests.

When the structure and content of the standard are profoundly revised in the new version, it is not always easy to make this comparison. For example, standard IEC 60601-1 used for medical electrical devices, the second version of which contained 447 inspection points while the subsequent version included 1,349 points. In some cases, the wisest solution may be to repeat the entire test programme, offering the greatest certainty of demonstrating compliance with all the requirements of this new normative reference framework.

► Identify the laboratory that will carry out the tests

The competence of the laboratory that carries out the tests is a question systematically covered during an audit by a certification body or an inspection by a national authority. It is therefore essential to question the choice of the laboratory that conducts the evaluation of its medical device.

Two situations are possible, depending on the applicable regulations or product certification rules:

• An internal laboratory on the Medical Device manufacturer's premises

The laboratory carries out the tests itself if it is recognised as competent and impartial regarding the results achieved. This most frequently means that it must provide certifying bodies or test authorities' documents regarding:

- the control of standards and test procedures to ensure repeatability of measurements
- an active regulatory and normative watch
- quality management meeting the requirements of ISO 17025, applicable to test laboratories
- the qualification and maintenance of the skills of test personnel
- operational maintenance and calibration of measuring equipment
- monitoring the environmental test conditions to be met

• An independent test laboratory recognised as competent

The requirements to be met in the previous case generally lead the manufacturer, whose principal competence is not conducting tests, to the solution of an independent external laboratory. However, the question of competence is still considered. Accreditation of the laboratory is the best possible evidence of competence. In France, the only accreditation body is COFRAC. Recognition of competence is administered using an 'accreditation schedule', listing the standards for which the laboratory is accredited.

In other countries, laboratory accreditation is issued by national bodies (usually only one per country). It is important to ensure that the foreign accreditation body for the laboratory is a member of ILAC (International Laboratory Accreditation Cooperation). Without however providing an absolute guarantee of international recognition for test results issued, the rules laid down by ILAC are intended to harmonise a minimum of practices and implement quality management systems for test laboratories.

To date, the only recognition offering real international value in more than 50 countries is CB accreditation issued by the IECEE (International Electrotechnical Commission for Electrical Equipment). This only covers electrical equipment.

► **Anticipate the sequence of tests**

The correct sequence of technical evaluation for a medical device is influenced by anticipating a certain number of practical questions:

• **The samples submitted for tests**

Factors to ensure include without being limited to:

- a sufficient number to optimise the length of the test campaign, assuming different tests can be carried out in parallel with each other.
- they must be representative of actual production (be careful about unfinished prototypes) or their configuration (different accessories, options for the medical device), making it possible to validate a range using the 'worst case', as described above.
- their possible destruction. Certain tests are deliberately destructive to validate the consequences of a catastrophic scenario.

• **Associated documentation**

The test parameters or determination of applicable tests may depend on information found in the technical documentation for the device to be evaluated. It may not be possible for the test laboratory to carry out certain tests if this information is not provided. For example, the maximum patient weight stated on the identification plate of an operating table of a medical bed is essential for carrying out mechanical strength tests.

The documentation required includes but is not limited to:

- The risk management file (e.g. Medical electrical device evaluated according to standard IEC 60601-1. Its contents combined with the suitability for use file is reviewed and can help to resolve non-conformances)
- Instructions for use, labelling and marking (including information essential for using the correct test parameters, such as maximum patient weights, frequency of the power supply, electrical operating voltages, degree of protection against moisture, etc.)
- Definition drawings, technical data (e.g. useful when preparing to fasten the sample on the test machine)
- List of critical electrical components (always requested when evaluating a medical electrical device)

• **The test schedule and sequence**

Anticipating preparation of the test programme in the laboratory also requires defining the appropriate test sequence. The planned sequence is not always given by the standards. A well-designed schedule optimises the time and therefore cost of tests (by combining tests, running them in parallel with several samples).

Some uncommon and specific test equipment may be needed (e.g. Faraday cage for Electromagnetic Compatibility, Anechoic Chamber, climatic chambers, vibrating bowl). Preparing the test schedule with the test laboratory ensures the availability of this equipment and the ability of the laboratory to carry out the tests.

Finally, it is important to plan for time dedicated to resolving non-conformances and correcting problems identified during the tests. A medical device is rarely compliant by chance. Ignoring this leads irretrievably to consequences for postponing the date the device may be placed on the market.

• **Support from the test laboratory and the assistance I need**

The complexity of the tests and expected evidence of compliance very often require support throughout the test campaign. It is wise, at the start, to define the company's expectations of the laboratory that will perform these tests. The interpretation of standards and results, technical support or direction towards design solutions consistent with normative requirements are all points to be covered beforehand, with the aim of building a custom and effective strategy.

► **Presenting the test results and conclusions**

The test report includes the results of the technical assessment of your device. This will be reviewed by a certification body or a national authority. Its content and presentation must therefore be well thought out in order to facilitate its recognition by the assessors to whom it will be submitted.

• **Language of the document**

Whatever the capabilities of the laboratory that performed the tests, an assessor in a foreign country targeted for your export will not be able to approve the test report if he is unable to understand it. It is therefore preferable to get it translated or to plan from the start to have it drafted directly in English.

• **Useful information to characterise the test**

The report should clearly show:

- the identification of samples tested and photographs of them
- the dated normative reference frameworks used for the evaluation and the sections applied for a partial test programme
- the dates the tests were carried out and the date the report was issued
- evidence of control of test equipment (accreditation, lists of calibrated equipment, test personnel, etc.)

This information will provide evidence for overall control of the evaluation carried out. A market certification or test body will certainly question you about this information if it is missing.

- **Clear presentation of the results**

Clear presentation of the test results is a factor that can speed up recognition of the report. The test results may be supported by graphs, records, data tables, calculations of uncertainty, etc. The report must include all data useful for reaching a decision about compliance. When this is not included, you can request it from your test laboratory.

- **An unambiguous conclusion**

When acceptance criteria are defined by a standard, the conclusions must be clearly shown (compliant, non-compliant, not applicable). Clearly visible and unambiguous conclusions will make it easier to review the report and so facilitate its admissibility.

- **The Certificate of Conformance**

The Certificate of Conformance associated with the test report is a summary tool showing that a satisfactory result was obtained.

The Certificate of Conformance must show the references for the device submitted for tests, the dated normative reference framework(s) used to evaluate compliance, the reference to the full report used to declare overall compliance and the issue date of the document.

► **In conclusion**

- **Defining a test strategy facilitates:**

- access to international markets
- dealing with developments of the medical device
- identifying partners that help test the medical device
- the sequence and time to carry out the tests
- recognition of the test reports

- **Defining a test strategy avoids:**

- technical and regulatory omissions for selling the Medical Device
- delays putting the device on the market
- additional expenditure to correct errors

MORE INFORMATION

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