



By this memo, we aim at clarifying compatibility issue, which we are facing when devices and accessories are connected to another medical device.

In our markets, we observe sales' growth of doubtful conformity accessories coming from various sources. If those accessories are imported by various kinds of distributors, it also happens they are imported by recognized companies who offer accessories for various brands of medical devices, sometimes through purchase groups.

We remain surprised that such situation can happen, knowing that CE marking regulations are strict, specifically when talking of mutual compatibility between medical devices.

We would like to point out risks when using products without proof of compatibility, as reminded by the French National Authority (AFSSAPS), attached.

Indeed, European Directive obliges manufacturers to supply proof of compatibility, whatever medical classification of the product is, including Class I category of products.

Main obligations to be fulfilled are:

- Identification labels and instructions of use, written as clearly as possible, which purchaser can trust if any incident
- Results of risks analysis
- Testing conformity of products with Essential requirements of MDD or harmonized European standards and being able to supply with its results of conformity, each time a new device is launched onto the market
- Traceability

INTEGRAL PROCESS applies EU directives to all its products since 10 years and more. Proves of compatibility per reference can be downloaded through our internet web site.

As per example, AFSSAPS has been reported several cases of exploding cuff bladders, when patient received a defibrillation choc. On the other hand, our cuffs line-up has been carefully tested following protocol developed in partnership with French notified body LNE/GMED

We cannot admit that an importer of medical accessories is not able to provide with such proves. It is important to notice that, in case of incidents, purchaser will have to explain its choice of purchase, involving his responsibility.

Attached document:

"Compatibility between medical devices" by the French Health Products Safety Agency (AFSSAPS) – April 2008



April 2008

French health products safety agency**Medical device evaluation division**

Market Surveillance Department

Matter handled by Pascal Di Donato

Email: pascal.di-donato@afssaps.sante.fr**Statement****Compatibility between medical devices**Preamble

Since it is consulted regularly on the question of compatibility between medical devices placed on the market by different manufacturers, Afssaps wished to make a statement by diffusing an information sheet for the attention of operators, buyers, users and manufacturers.

The regulation (article 12 of European directive 93/42/EEC) has made special provision for systems and procedure packs intended for assembly with a view to constituting a device. In such cases, the person responsible for placing it on the market produces an assembly of several medical devices and if applicable, affix the CE mark to the system. Since this situation is clearly covered by the regulation, Afssaps decided to deal with cases where different combined medical devices are placed on the market separately by different manufacturers.

Whether or not it is a case of an accessory of a medical device, as defined in directive 93/42/EEC, which specifies that an accessory is treated as a medical device in their own right, the compatibility between two medical devices must be demonstrated.

This document has been drawn up to explain the conditions for placing on the market medical devices which claim to be compatible; therefore, it does not cover questions of a commercial nature, in particular the contractual guarantees specified in purchasing conditions.

Finally, it should be noted that this statement does not apply in the case of implantable medical devices.

Situations encountered on the market

Several situations exist:

- **Medical device presented as "captive" by the manufacturer**
The manufacturer places a medical device on the market, mentioning in the instruction for use, on the one hand a list of its own compatible medical devices and on the other hand, in the restrictions on use, that the medical devices of other manufacturers are not compatible and should therefore not be used.
- **Open medical device with information on compatibility**
The manufacturer places on the market a non-captive medical device and in its instruction for use recommends the use of medical devices of other manufacturers, or describes their characteristics (e.g.: compliance with a standard, technical specifications, etc.).
- **Medical device without information on compatibility**
The manufacturer places a medical device on the market and gives no information on compatible medical devices in its instruction for use.

Regulatory context

The concept of compatibility between medical devices is dealt with in annex I of directive 93/42/EEC relating to the essential requirements applicable to medical devices, under the following points:

- Point 9.1: *"If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use."*
- Point 13.6.c: Where appropriate, the instruction for use must contain the following particulars: [...] "if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination".

Manufacturers' obligations

Characteristics and performance

In application of point 13.6.c of annex I of directive 93/42/EEC, the manufacturer must describe the characteristics of its product in its instruction for use in order to identify the devices which must be used to obtain a safe combination. It is recommended that the manufacturer indicates explicitly the references of the medical devices concerned.

In application of point 13.6.b of the same annex of the directive, the manufacturer of a medical device presented as compatible must describe the performances of its product.

The performance of the new combination may be different from the original combination, and must make it possible to fulfil the intended purpose.

Standardisation

Standardisation is one of the most appropriate solutions for demonstrating compatibility. Compliance with a harmonised European standard gives presumption of conformity with the essential requirements of directive 93/42/EEC. In the absence of a harmonised European standard, the manufacturer can use a national or international standard, provided it is able to demonstrate that it complies with the requirements applicable to it. Thus, in many cases, the fact that a manufacturer follows the standard is a sufficient criterion for establishing the compliance of a medical device intended to be used in combination.

Demonstration of compatibility

A manufacturer of medical devices may claim compatibility with another medical device even if the manufacturer of the latter disputes the use of medical devices of other manufacturers. It must then have demonstrated its product's compatibility with the medical device with which it is associated and ensure the continuity of that compatibility over time in the event that the medical device with which it is associated is upgraded.

To demonstrate compatibility and comply with the essential requirements of directive 93/42/EEC, the manufacturer of the medical device must in particular:

- Be compliant with the European harmonised standards on safety and performance, if such exist, or prove an equivalent level of safety and performance;
- Carry out an adequate risk management process to:
 - o Demonstrate that the use of its device does not engender any additional risks vis-à-vis the original device;
 - o Analyse any change in performance and safety of the new combination;
 - o Define the procedures which make it possible to monitor over time the upgrades of the medical device with which it is associated and evaluate the technical performance of the combination.
- Carry out technical and/or clinical tests, or prove that these are not necessary.

These requirements are identical whatever the class of medical device and whatever the level of intervention of the notified body required during conformity assessment procedure of CE marking compliance chosen by the manufacturer responsible for placing the medical device on the market and for its claims, in particular in terms of compatibility.

Recommendation to users

It is indispensable to verify the claims of the manufacturer of the medical device announced as compatible in its instruction for use. In fact, the instruction for use is the fundamental element which makes it possible to explicitly determine the claims which involve the manufacturer's responsibility.

It should be noted that if a certificate of compatibility is proposed, it cannot go further than what the manufacturer claims in the instruction for use of its medical device and therefore contributes nothing.

In other words, it is the instruction for use which attests to and which must inform the user of the claimed compatibility. (The instruction for use is a document in the name of the responsible of the CE marking and bearing the CE marking of conformity. It contains all the information described for under point 13.6 of annex I of directive 93/42/EEC).

There are thus three approaches:

- The manufacturers of medical devices to be combined claim compatibility in their respective instructions for use. In principle, this case does not require any particular procedure by the buyer.
- The manufacturer is the only one to claim compatibility with another medical device in its instruction for use. In case of doubt, the buyer may request elements demonstrating such compatibility.
- The manufacturer of a medical device presented as compatible does not set out a list of compatible devices in its instruction for use (in cases where the list would be too long). The buyer may, as a precaution, ask the manufacturer for confirmation that the combination it wishes to make is actually possible.

In a situation where neither of the two manufacturers claims compatibility, the user's responsibility is liable to be involved in the event of an incident.

Afssaps' missions

Medical devices vigilance

Pursuant to article L. 5212-2 of the French Public Health Code, any incident or risk of incident involving a medical device that lead or might have led to the death or serious deterioration of the state of health of a patient, user or third party is to be reported to Afssaps without delay.

The report form may be downloaded from the Afssaps website (www.afssaps.sante.fr), tabs: "Infos pratiques / Signalement des vigilances".

The reports are to be forwarded to Afssaps /Département des vigilances – Fax: +(33)1.55.87.37.02.

In the event that an incident (or the risk of an incident) should involve two medical devices whose claims in terms of compatibility are contradictory:

- The medical device which disputes the association could be called into question if the source of the incident is independent of the compatible medical device used.
- The medical device which claims compatibility could also be called into question if the manufacturer of that device is not able to demonstrate that compatibility.

Market surveillance

Afssaps may at any time institute procedures for monitoring the conditions for placing products on the market and take the necessary measures in case of danger or a breach of the regulations.