



**Therapeutical Hyperbaric
System in Europe are
medical devices:
consequences**

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European Directives: fundamental principles

Limit legislative harmonization to the essential requirements that are of public interest

Essential requirements are designed to provide and ensure a high level of protection

The essential requirements are set out in annexes to the directives



In summary:

the New Approach requires that the standards offer a guaranteed level of protection with regard to the essential requirements established by the directives.

So,

A harmonized standard (EN norm) must match the essential requirements of the relevant directive.

Difference between Legislation and Normalisation

This legislative form does not anymore impose precise technical specifications

The manufacturer has, indeed, the obligation to prove that his products are in conformity with the essential requirements of the concerned directive.

...the application of the directive's regulation can vary, following which norm has been retained and what registered organ is in charge of certification.

A photograph of a modern hospital operating room. The room is brightly lit with overhead surgical lights. In the center, there are two surgical tables covered with blue drapes. The walls are white and feature various medical equipment, including monitors and control panels. The floor is a light-colored, polished surface. The overall atmosphere is clean and professional.

European standards must be transposed at national level

The European standards organizations (via the CEN) are responsible for identifying and elaborating harmonized standards

In summary:

The conformity assessment is based on

- manufacturer's internal design and production control activities;**
- third party type examination combined with manufacturer's internal production control activities;**
- third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification;**
- third party unit verification of design and production; or**
- third party approval of full quality assurance systems.**

Difference between Legislation and Normalisation

The load to translate into technical language (norms) is been taken care by the normalisation organisations (CEN)

The European norms, after being harmonised, are recognised as being in conformity with the requirements of the concerned directive

- **The "great" difference between these two Directives is that one (93/42) deals with the medical device which is the HBO, while the other (97/23) retains only the aspect relative to the construction of the pressure vessels.**



Extracts of preamble to EC Directive 93/42

... the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market

... the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive

... whereas the classification rules are based on the vulnerability of the human body ...

Extracts of EC Directive 93/42

Article 3 Essential requirements

The devices must meet the essential requirements which apply to them, taking account of the intended purpose of the devices concerned.

Article 9 Classification

1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX.

For the record, medical devices are classified in different categories owing to the presented risks. The classification that applies for the 'multiplace' therapeutic hyperbaric chambers is IIb.

Classification of the HBOT Facilities following EC Directive 97/23

This Directive applies to a broad type of equipment under pressure, which range from a gas lighter to apparel representing a high potential danger.



Classification of the HBOT Facilities following EC Directive 97/23

The hyperbaric chambers are part of the category III, provided that the pressure does not exceed 4 bar.

If this pressure is overreached, they will be classified in category IV.



Choice of a norm

First of all, we should remember not to confuse:

**the hyperbaric chamber (the container/ vessel)
with
the hyperbaric chamber (as the medical device)**

**Regarding the container (pressure vessel) and the
Medical device, there are both norms AND a
European Directive.**

Choice of a norm

One should remind that the choice of a norm - and afterwards proposing it to the notified body - falls within the competence of the manufacturer (for lack of an international standard).

Nevertheless, by keeping account of what has been previously reported, it is strongly recommended to suggest a norm, if not to impose it !

The background image shows the interior of a hyperbaric chamber. It is a cylindrical space with a light-colored, possibly metallic, wall. In the center, there is a door with a circular porthole. To the right, there is a control panel with several buttons and a small display. The floor is dark, and there are some blue seats or mats visible. The overall lighting is bright and even.

**What European norms exists these days
on the market ?**

EN 13445 for the pressure vessels

EN 14971 for the medical devices

EN 14931 for the HBO systems

EN 16081 for the Fire Extinguishing Systems



Thank you,
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