XCDC Trading & Consultancy B.V.B.A.
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BTW nr. : BE 0524 895 308

DIRECTIVE MEDICAL DEVICES 93/42/EC

The European **Medical Device Directive 93/42/EC** is legislation on European Level applicable **from 14/06/1993**. This directive has since been amended several times. The last substantial amendment of this directive was the version 2007/47/EC. With the transposition of this Directive into national law in each Member State of the European Community, this Directive became mandatory.

A "Medical Device" is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. In other words, this legislation is not applicable on "medicines".

Examples of medical devices:

- Gas distribution networks for compressed medical gases (such as oxygen, breathing air, nitrous oxide), for vacuum (EN ISO7396-1) and for the evacuation of anaesthetic gases (EN ISO7396-2).
- Liquefied gasses such as Nitrogen (N_2) and carbon dioxide (CO_2) for use in cryotherapy
- …

The medical devices are classified into different classes, namely I, I_{ster}, I_{meas}, IIa, IIb en III (see annex IX). Depending on the classification, the manufacturer of the medical device must follow on of the assessment procedures as described in annex II to VIII of the Directive. In any case, he must draw up a technical file. In addition, in most cases, the choice for the implementation of a quality assurance system is economically the most beneficial route. For the preparation of the quality system, the application of the harmonized standard EN ISO13485 (2012) is recommended.

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Based on our years of experience in inspecting and auditing of medical devices, we can offer you the following services:

- Preparation of technical files in accordance with the legislation
- Preparation and implementation of the quality assurance system in accordance with the legislation MDD93/42/EC and the harmonized standard EN ISO13485.
- Preparation of hazard analysis (EN ISO14971) en clinical evaluation (Annex X)
- Training related to the legislations and used (harmonized) standards
- Contacts with Notified Bodies
- Assistance in the implementation of external audits
- Conducting internal audits
- Develop action plans, resulting from internal and external audits
- …

In relation to "Distribution network for compressed medical gasses and vacuum an" and to "Systems for the evacuation of anaesthetic gasses" in hospitals and nursing homes, we can offer you the following services as well:

- Technical evaluation of the existing system to the requirements of the legislation and the applicable standard(s);
- Preparation of an action plan in order to render the existing installations in conformity with the legislation and standards;
- Evaluation of the documentation available for the existing installations;
- Execution of tests on existing installations, modifications of existing installations and new installations, based on the requirements of the standard
- Perform analysis on medical gases (compressed air) (laboratory analysis or on site)
- Preparation of specifications and technical dossiers in accordance with the legislation and the standard for new Construction projects;
- Preparation of a risk management plan in accordance with annex G of the EN ISO7396;
- Follow up of new projects, extensions, modifications, renovations.

If you are interested in our services, do not hesitate to contact us. We can make an appointment to define the desired services. After that, we are able to give you an open quotation.