Certification of PSA Oxygen Generators to the Medical Device Directive 93/42/EC.

An overview for partners and customers.

Classification to 93/42/EC

According to the directive 93/42/CE, medical devices are divided in four product classes based on the vulnerability of the human body taking account for the potential risks associated with the technical design and the manufacture of the devices:

Class	Vulnerability Level	Conformity Assessment Requirements & Procedures	
I	Low	Annex V + Annex VII	Self-assessment by the Manufacturer
IIA	Low – Medium	Annex V + Annex VII (manufacturing stage only)	Assessment by Notified Body according to Annex V + Annex VII
IIB	Medium – High	Annex II – Section 3 (design and manufacturing stage)	Assessment by Notified Body according to Annex II – Section 3
III	High	Annex II	Assessment by Notified Body according to Annex II

The deciding condition for the classification of PSA medical oxygen generators for hospitals is Rule 11 of Annex IX of the MDD 93/42/CE. Ventilators and respirators are all defined as "active devices" belonging to Class IIB. When a connection exists between a non-active device (like a PSA medical oxygen generator) and an active device (like a patient-interactive ventilator/respirator), where the non-active device forms a link in the transfer of the substance (Oxygen) between the patient and the active device, and the safety and performance of the active device is influenced by the non-active device, the classification of the active device will have to be applied to the non-active device as well. This means that PSA medical oxygen generators have to be in Class IIB.

In other words, PSA medical oxygen generators classified as Class IIA medical devices can be used for conscious and spontaneously breathing patients only, where failure to deliver the appropriate dosage characteristics is not potentially hazardous. If oxygen is required for unconscious or non-spontaneously breathing patients, like intensive-care patients in hospitals, who need oxygen enriched breathing air (40 vol.% of oxygen or more) through orotracheal intubation 24 hours a day, the PSA medical oxygen generator has to be certified as a Class IIB medical device according to Rule 11.

Additionally it should be noted that medical gas pipeline systems are generally considered Class IIB medical devices based on ISO 7396-1:2007. (ref.: Notified Body No. 0434).

Conclusions

1. **PSA Medical Oxygen Generators for medical oxygen supply to hospitals have to be classified as Class IIB Medical Devices of the MDD 93/42/EC.**

2. **As a consequence, the conformity assessment procedure has be according Annex II – Section 3 of the MDD 93/42/EC.**

3. **A classification as Class IIA (certification to Annex V + Annex VII) would only be possible for oxygen concentrators for oxygen therapy at home.**

What does IGS guarantee you?

1. A certified quality management system according to both ISO 9001:2000 and ISO 13485:2003 for the design and manufacturing of the OXYSWING® PSA Medical Oxygen Generators;

2. An EC-type examination certification according to Annex II – Section 3 for the OXYSWING® PSA Medical Oxygen Generators, issued by Det Norske Veritas (DNV);

3. An unlimited flexibility in the selection and lay-out of a medical oxygen supply system through its patented OXYSWING® Modular PSA Medical Oxygen System.

For further information, please contact:

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