CLINICAL EVALUATION REPORT

Compiled by

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Signed By

John Lamb

Oxygen Sensors

1. General details

Medical Oxygen Sensors

Part Numbers: See DOCID 16701

Virtual Manufacturer:

Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT

Significant Manufacturer:

Envitec-Wismar GmbH
Alter Holzhafen 18, D-23966 Wismar

2. Description of the device and its intended application.

Oxygen Sensors are intended as oxygen sensing component of an oxygen analyser that measures oxygen concentration in breathing gas mixtures in applications such as:

Sensing device for oxygen in control device oxygen concentrators
Sensing device for oxygen in medical ventilators
Sensing device for oxygen in anesthesia equipment
Sensing device for oxygen in incubators.

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases.

3. Intended therapeutic and/or diagnostic indications and claims

Oxygen sensors are based on the principle of electro-galvanic sensors. They are constructed in a plastic housing containing two electrodes , a precious metal cathode and an anode immersed in a liquid electrolyte medium. Electrically the device resembles a low voltage battery cell. A gas permeable diffusion membrane provides the interface to the gas sample. The oxygen gas is reduced on the sensing electrode and the anode is oxidized. The resulting current produces an external electrical voltage signal on the load resistor that is proportional to the conversion of the oxygen. The sensor signal is temperature dependent and typically compensated with an internal temperature compensating resistor network.

4. Context of the evaluation and choice of clinical data types.

The Clinic Evaluation has been performed via, Clinical Experience data / documentation, and historic records

Sources of data/documentation used in clinical evaluation.

Review Viamed Risk Assessment current DOCID 20852
Envitec Risk Assessment Report current DOCID 20850
Envitec Clinical Evaluation Report DOCID 20854

Post-market Surveillance report:

Section 1 Stock Identification

Section 2 Supplier Review

Section 3 Sales Review

Section 4 Countries Review

Section 5 Returns / Services Review

Section 6 Design Changes Review

Section 7 IFU Review

Section 8 Labels Review

Section 9 Documentation updates Review

Section 10 Internal Issues Review

Section 11 Clinical Data / FDA Incidents Search

Current DOCID 20115

All returns / failure records since 2001 are computerized and reviewed annually.

See post market surveillance reports DOCID 20115.

Sales / Returns data See DOCID 20115

Viamed has continually supplied oxygen sensors since 1977.

5. Summary of the clinical data and appraisal

There have been no clinical trials carried out on behalf of Viamed or Any other manufacturer of oxygen sensors. However the use of oxygen monitoring using Galvanic sensors was introduced over 40Years ago, Largely introduced to the UK market by Viamed in 1977.

Viamed have supplied over the course of **40** Years **Teledyne, Maxtec, Envitec** manufactured Sensors, all Q.A. and Returns data is recorded and monitored. There have been **No** cases identified that resulted in a hazardous situation.

As per DOCID 20854.

Envitec have supplied Oxygen sensors for 20 Years, Envitec have reviewed 10 Years of data and found No cases that resulted in a hazardous situation.

Due to the long-term market experience without hazardous situations, by either Viamed Or Envitec the residual risk is evaluated as acceptable.

Oxygen sensors are considered to be safe in the scope of the European Directive 93/42/EEC directive for the application and intended use as described.

Signed _____

Date _____