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MEDICAL DEVICES AGENCY

Safeguarding Public H

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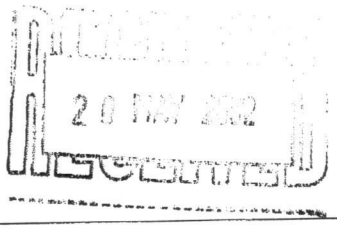

Our Ref: CMY 203/PCC
Direct Line: 0207 972 8220
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Date: 15 May 2002

Dear Mr Lamb

OXYGEN HOODS

MDA has recently had cause to review the classification of Oxygen Hoods under the Medical Devices Regulations and are minded to conclude that they should be considered as Class IIa rather than Class I. In our view Oxygen Hoods come under rule 2 of the classification criteria specified in Annex IX of the Medical Devices Directive 93/42/EEC which is transposed into UK law by the Medical Devices Regulations 1994 (as amended by SI 2000 No. 1315).

Rule 2 states that non-invasive devices intended for the channelling of gases for the eventual infusion into the body are Class IIa if they are attached to an active medical device in Class IIa higher. MEDDEV 2.4/1 defines that a connection is deemed to exist between an active and a non-active device where a non-active device forms a link in the transfer of the substance between the patient and the active device and the safety and performance of one of the device influenced by the other device. Oxygen has to be converted to ambient pressure by a pressure regulator which is an active device and influences the performance of the Oxygen Hood. Hen Oxygen Hoods should be classed as Class IIa medical devices.

Your company have registered a product of this category as a Class I device with MDA under Regulation 14 of the Regulations and the purpose of this letter is to ask for your comments before a final determination is reached.

Registration is based on your declaration that the device is in compliance including being correctly classified and we do not examine each individual notification. So acceptance of the registration does not represent any form of accreditation or approval of the device by the UK Competent Authority.

The conformity assessment route for Class II a devices requires the manufacturer of the device to obtain conformity assessment certification from a designated notified body. However if we do come to the eventual conclusion that these devices are Class IIa we would be prepared for the device to remain on the market while corrective action is taken as long as it can be completed within a reasonable timescale and no safety difficulties arise in the meantime. Furthermore you would also be able to challenge the change in classification through the appeals process which can involve independent adjudication if you disagree with the final determination. Details of the appeals procedure will be sent to you when this stage is reached.

We would be grateful for your comments on the above within 28 days of the date of this letter please.

Yours sincerely

J Worroll

JOHN WORROLL
Section Head, Regulatory Affairs