

CE Declaration of Conformity

It is hereby declared that the product **Salitair** conforms to the requirements for a class I Medical Device as per the European Medical Device Directive 93/42/EEC and amendment thereto as transposed into UK legislation.

Salitair has been listed as a Class I device with the UK Competent Authority the Medicines and Healthcare Products Regulatory Agency (MHRA) (Ref: CA 010231).

The required technical documentation has been prepared and an appropriate vigilance procedure is in force as per annex VII of the medical device directive.

The product meets the Essential Requirements set out in annex 1 of the medical device directive.

Signed\...

Dated: 20/06/2017

For and on-behalf of the Manufacturer, Medi-Direct International Ltd*, being a duly authorised person

Name: Jason Timms

Position: Managing Director; Medi-Direct International Ltd

*Medi-Direct International Ltd is a UK registered limited company and is responsible for placing the device on the market in the EU.

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