

Declaration Ref No: DC11-0001

CE Declaration of Conformity

We,
Atlas Medical

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Declare our responsibility that the following product:

ASO Latex Kit

Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003)
supported by Lloyd's certificate and complies with the essential requirements of

In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I

And

EN 18113-1, -2 :2011, EN ISO 15223:2012

EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999,

EN ISO 13612:2002, EN ISO 13641:2002

And

Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the
product Lot Log.

Manufacturer

Atlas Medical

William James House, Cowley Rd.

Cambridge, CB4 0WX, UK



Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F. 10 08.02.2011
	Augsut-2003	21.10.2015		