

Declaration Ref No: DC11-0011

## **CE Declaration of Conformity**

We, Atlas Medical

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Declare our responsibility that the following product:

## RPR Carbon Antigen

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 CB0 4WX, UK



Atlas	First issue date	Date of rev <mark>iew</mark>	Management approval	MRXDO10F.
Medical	Augsut-2003	06.11 <mark>.2</mark> 016	& Blill	10 08.02.2011