

Declaration Ref No: DC11-0049

CE Declaration of Conformity

We,
Atlas Medical

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Declare our responsibility that the following product:

TPHA 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
And

EN ISO 18113, -2,-4:2011, EN ISO 15223:2012
EN ISO 13532: 2002, 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
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Cambridge, CB4 0WX, UK

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 01.10.2012
	October-2003	27.01.2016		