

Declaration Ref No: DC11-0048

CE Declaration of Conformity

We,
Atlas Medical

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Declare our responsibility that the following product:

SLE 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.

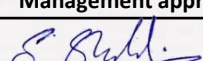
Manufacturer

Atlas Medical

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