

Declaration Ref No: DC20-0005

## CE Declaration of Conformity

We,  
**Atlas Medical**

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Declare our responsibility that the following product:

### **Covid-19 IgG/IgM ELISA Kit**

Is produced under Atlas quality system : (ISO13485: 2016) supported by Lloyd's certificate and complies with the essential requirements of

### **In Vitro Diagnostic Medical Devices Directive 98/79/EC**

And

EN 18113-1, -2,-4:2011, EN ISO 15223:2016  
EN ISO 14971:2012, EN ISO 23640:2015, 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**  
**Ludwig-Erhard Ring 3**  
**15827 Blankenfelde-Mahlow Germany.**



Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
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