Atlas Medical

Declaration Ref No: DC20-0007

CE Declaration of Conformity

We,

Atlas Medical

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Declare our responsibility that the following product:

Covid-19 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
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	Mar-2020	6/4/2020		