Declaration Ref No: DC11-0051

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow
Tel: +49 - 33708 – 3550 30
Email: info@atlas-medical.com

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
Tel.: +962 6 4026468
Fax: +962 6 4022588
Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	December.2011	28.09.2020		

Atlas Medical
Quality Diagnostic Products

Digitally signed by Monastîrschii Viorica
Date: 2020.11.09 17:17:22 MSK
Reason: MoldSign Signature
Location: Moldova

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls).
ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
Streptococcus Latex Kit, 6 Groups, 6x50 Tests.
D-Dimer Latex , 100 Tests.
RPR Syphilis Kit, 500 Tests (10 ml latex, 2x1ml control) Without card,stirring sticks.
RPR Carbon Antigen Kit, 1000 Tests.