Declaration Ref No: DC11-0051

Atlas Medical

CE Declaration of Conformity

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

We,

Atlas Medical

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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 Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2012, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

Intended for In-Vitro Professional use only.

"SANMEDICO"

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	26.11.2019		

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

RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests.
CRP Latex Kit, 100 Tests (4ml Latex, 2x1.0ml Controls).
RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control).
RPR Carbon Antigen Kit, 100 Tests
D-Dimer Latex Kit, 100 Tests
Streptococcus Latex Kit, 6 Groups, 6x50 Tests (6x2ml Latex, 1.0ml Positive Control, 2x10ml Extraction Enzyme. Glass Slide).
Drabkins Reagent, 40x, 6x50ml (3000 Tests).
Drabkins Reagent, 40x, 50ml/vial (500 Tests).
RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
VDRL Antigen Kit,(5 ml+ 55 ml buffer+3 ml positive control + 3 ml negative control)
TPHA Kit, 100 Tests
Staphylococcus Latex Kit, 100 Tests (4ml Test Latex, 2ml Control Latex, Glass Slide).

REPUBLICA MOLDOVA S.R.L. "SANMEDICO"

Atlas Medical
Quality Diagnostic Products