

Declaration Ref No: DC21-0035

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 GMED:

Certificate N⁰.: 36655 rev 1 Expiry Date: October 8 th.2023

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
Blankenfelde-Mahlow, Germany.

Blanken	felde-Mahlow , G	Germany.	Atlas Medical Atlas Medical	
Atlas Medical	Issue date	Date of review	Quality Diagnostic	MRXDO10F.10
	March.2021	09.03.2021		08.02.2011



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Product Description		
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).		
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)		
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)		
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests		
8.00.13.0.0300: Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex		
(A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E,		
1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent		
3, Stirring Sticks, Glass Slide).		
8.00.18.3.0500: RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control)		
Without card, stirring sticks.		

8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

