

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 (Annex I) 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 N°: 36655 rev 1
Expiry Date: October 8th.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

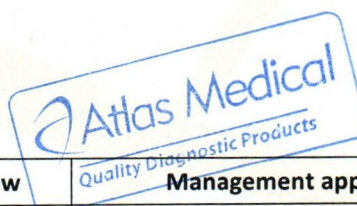
Intended for In-Vitro Professional use only.

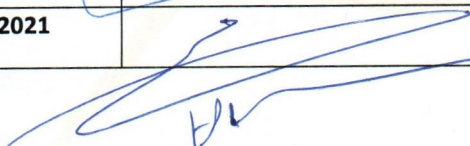
Manufacturer

Atlas Medical

Ludwig-Erhard-Ring 3

Blankenfelde-Mahlow , Germany.



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|------------------|------------|----------------|--|-------------|
| Atlas Medical | Issue date | Date of review | Management approval | 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). |

