

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.
- 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



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| 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. |

A handwritten signature in blue ink is written over a blue rectangular stamp. The stamp contains the Atlas Medical logo and the text 'Atlas Medical' and 'Quality Diagnostic Products'.