

# CE Declaration of Conformity

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

We,  
**Atlas Medical**

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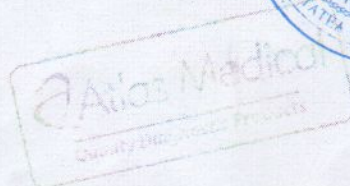
Declare our responsibility that the following product:

### See Attached list

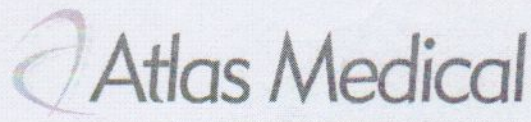
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by Lloyd's Register Quality Assurance.
- 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

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



|               |               |                |                     |                           |
|---------------|---------------|----------------|---------------------|---------------------------|
| Atlas Medical | Issue date    | Date of review | Management approval | MRXDO10F.10<br>08.02.2011 |
|               | December.2011 | 26.11.2019     |                     |                           |



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|---|
| 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).                                       |

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Quality Diagnostic Products





**CERTIFICAT**  
**CERTIFICATE OF REGISTRATION**  
**N° 36655 rev.0**

**GMED certifie que le système de management de la qualité développé par**  
*GMED certifies that the quality management system developed by*

**ATLAS MEDICAL GmbH**  
**Ludwig-Erhard-Ring 3**  
**15827 Blankenfelde-Mahlow GERMANY**

**pour les activités**  
*for the activities*

**Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .**

*Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.*

**réalisées sur le(s) site(s) de**  
*performed on the location(s) of*

**Voir addendum**  
*See addendum*

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*

**ISO 13485: 2016**

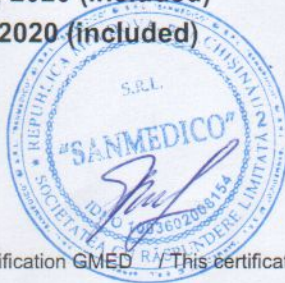
**Début de validité / Effective date March 23rd, 2020 (included)**

**Valable jusqu'au / Expiry date : October 8th, 2020 (included)**

**Etabli le / Issued on : March 23rd, 2020**



**CERTIFICATION DE SYSTEMES DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités et portée disponible sur [www.cofrac.fr](http://www.cofrac.fr)



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

DocuSigned by:  
*Béatrice LYS*  
ID: 36655 rev.0

GMED N° 36655-0

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

GMED\_SQ\_plusSites-FV0-07-2018

**GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459**  
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