

## CE Declaration of Conformity

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

We,  
**Atlas Medical**

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Tel.: +962 6 4026468  
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Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

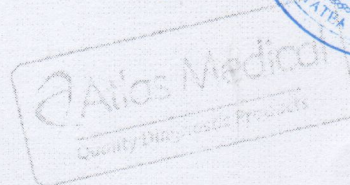
Declare our responsibility that the following product:

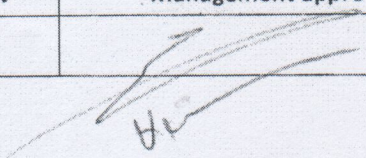
### See Attached list

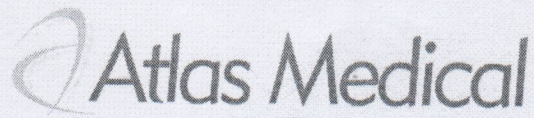
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by Lloyd's Register Quality Assurance.
- 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
	December.2011	26.11.2019		08.02.2011



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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).





**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**

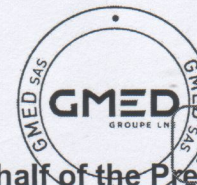
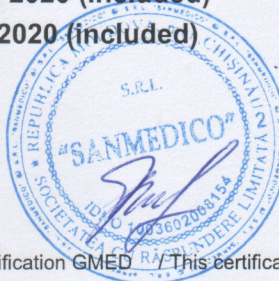
**Début de validité / Effective date March 23rd, 2020 (included)**

**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)



DocuSigned by:

*Béatrice LYS*

**On behalf of the President**

**Béatrice LYS**  
**Technical Director**

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



Addendum au certificat n° 36655 rev. 0 page 1/1  
Addendum of the certificate n° 36655 rev. 0  
Dossier / File N°P172375

**Ce certificat couvre les activités et les sites suivants :**  
*This certificate covers the following activities and sites:*

**French version :**

**Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.**

**English version:**

*Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for self-testing, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.*

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

French version:

**Siège social, responsable de la mise sur le marché**

*English version:*

*Headquarter, legal manufacturer*

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**Sahab Industrial Zone Area  
King Abdullah II Industrial City  
Amman 11512  
JORDAN**

French version:

**Conception, fabrication et contrôle final**

*English version:*

*Design, manufacture and final control*

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**William James House  
Cowley Road,  
Cambridge, CB OWX  
United Kingdom**

French version:

**Contact réglementaire**

*English version:*

*Regulatory Administration*

\*\*\*\*\*

**3 sites / 3 sites**



DocuSigned by:

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