

Declaration Ref No: DC21-0035

## **CE Declaration of Conformity**

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

We,

**Atlas Medical**

Head office: Ludwig-Erhard-Ring 3  
Blankenfelde-Mahlow, Germany.  
Tel: +49 - 33708 – 3550 30  
Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.  
Tel.: +962 6 4026468  
Fax: +962 6 4022588  
Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Declare our responsibility that the following product:

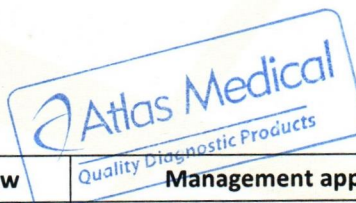
**See Attached list**

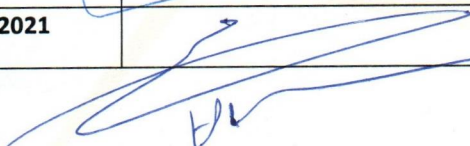
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:  
**Certificate N°:** 36655 rev 1  
**Expiry Date:** October 8<sup>th</sup>.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.**



|               |            |                |                                                                                      |                           |
|---------------|------------|----------------|--------------------------------------------------------------------------------------|---------------------------|
| Atlas Medical | Issue date | Date of review | Management approval                                                                  | MRXDO10F.10<br>08.02.2011 |
|               | March.2021 | 09.03.2021     |  |                           |

## CE Declaration of Conformity

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

| 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).                                                                                                                                                                                                          |



Declaration Ref No: DC21-0169

## CE Declaration of Conformity

We,

### **Atlas Medical**

Head office: Ludwig-Erhard-Ring 3  
15827 Blankenfelde-Mahlow Germany

Tel: +49(0)33708355030

Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.

Tel.: +962 6 4026468

Fax: +962 6 4022588

Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Declare our responsibility that the following product:

| Product Code   | Product Name                                                        | Class       | GMDN code |
|----------------|---------------------------------------------------------------------|-------------|-----------|
| 8.00.18.3.1000 | RPR Carbon Antigen (Coarse Grain) Kit,<br>1000 Tests (Reagent only) | General-IVD | 32450     |

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate:

**Certificate N°**.: 36655 rev 1

**Expiry Date**: October 8<sup>th</sup>.2023

and complies with the essential requirements of

**In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I**

**And**

**EN 18113-1, -2,-4:2011, EN ISO 15223:2016**

**EN ISO 14971:2019, EN ISO 23640:2015, ISO 2859/1:1999,**

**EN ISO 13612:2002, EN ISO 13641:2002.**

**And**

Intended for In-Vitro Professional use only.

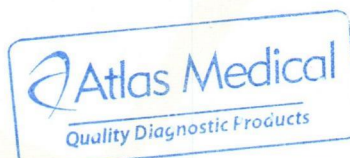
This Declaration includes the batches produced beyond this day according to the product Lot Log.

### **Manufacturer**

**Atlas Medical**

**Ludwig-Erhard-Ring 3**

**15827 Blankenfelde-Mahlow Germany.**



|               |                  |                |                                                                                      |                           |
|---------------|------------------|----------------|--------------------------------------------------------------------------------------|---------------------------|
| Atlas Medical | First issue date | Date of review | Management approval                                                                  | MRXDO10F.10<br>08.02.2011 |
|               | Dec.2021         | 09.12.2021     |  |                           |

**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 October 9th, 2020 (included)**

**Valable jusqu'au / Expiry date : October 8th, 2023 (included)**

**Etabli le / Issued on : October 8th, 2020**

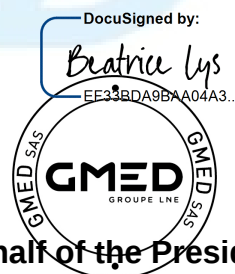


**CERTIFICATION  
DE SYSTEMES  
DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

GMED N° 36655-1

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

Renouvelle le certificat 36655-0



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

**GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459**  
**Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • [gmed.fr](http://gmed.fr)**

**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*

\*\*\*\*\*

**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*

\*\*\*\*\*

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

French version:

**Contact réglementaire**

*English version:*

*Regulatory Administration*

\*\*\*\*\*

**3 sites / 3 sites**

DocuSigned by:

*Beatrice Lys*  
EF33BDA9BAA04A3...  


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