

## STATEMENT

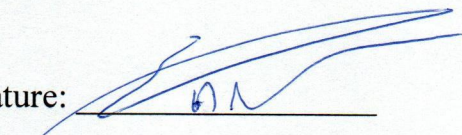
We, ATLAS MEDICAL having a registered office at Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

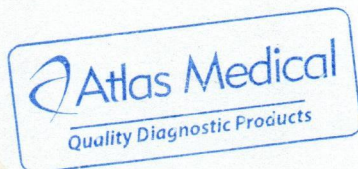
On behalf of manufacturer:-

General Manager

Haya Amawi

Signature: 

Date: 15.01.2022



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Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Germany. Tel: +49 33 70 83 55 030

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK. Tel: +44 1223 858 910

Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan

## CE Declaration of Conformity

We,  
**Atlas Medical GmbH**  
 Head office: Ludwig-Erhard-Ring 3  
 15827 Blankenefelde-Mahlow Germany  
 Tel: +49(0)33708355030  
 Email: info@atlas-site.com

Middle East Site: : Sahab Industrial Zone Area, King Abdullah II Industrial City  
 Amman 11512, 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:

**Blood Grouping Reagents:**  
 (Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent , Anti-AB Monoclonal Reagent and  
 Anti-D IgG/IgG blend Reagent)  
 see the attached list of variants

That are classified as Annex II, list A

Is produced under Atlas quality system (ISO13485: 2016) supported by GMED certificate and  
 complies with the essential requirements of

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

And

EN ISO 18113-1, -2 :2011, EN ISO 15223:2016  
 EN ISO 14971:2019, EN ISO 23640 :2015 , ISO 2859 :2017,  
 EN 13612:2002, EN 13641:2002 , EN 13975:2003,  
 EN ISO 13485:2016, EN 62366-1:2020

And

Intended for In-Vitro Professional use only.

### Conformity Assessment Route:

Annex IV.3 –Approval full Quality Assurance System.

Annex IV.4-EC Design Examination (of the product)

### Notified Body:

G-MED	<b>CE</b>	0459
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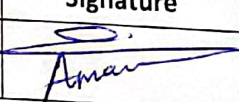
GMED, Laboratoire national de métrologie et d'essais

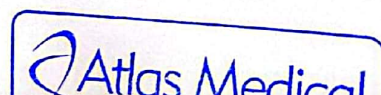
1 rue Gaston Boissier 75015 Paris

Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

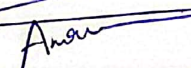
### EC Certificates No.:

- CE Certificate of Approval full Quality Assurance System: 33540 rev4.
- CE Certificate Of EC Design Examination: 33544 rev3.

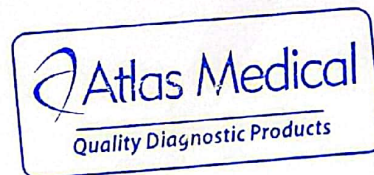
Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 <sup>th</sup> october 2017	26 <sup>th</sup> May 2025	Amani Al-habahbeh (RA Manager)		

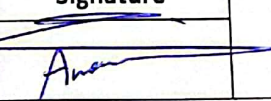


Product Code	Product Name	GMDN Code
8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/Carton Box	52532
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials / Plastic Pack	52532
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials / Carton Box	52532
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, / Carton Box	52538
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials / Plastic Pack	52538
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials / Carton Box	52538
8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/ Carton Box	46442
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack	46442
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/Carton Box	46442
8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/ Carton Box	52647
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials / Plastic Pack	52647
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials / Carton Box	52647
8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/Carton Box	52532
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials / Plastic Pack	52532
8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	52538
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials /Plastic Pack	52538
8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)),3x10ml / plastic Pack	45308
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml /Plastic Pack	52695
8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/Carton Box	46442
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,10 vials /Plastic Pack	46442
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial,18 vials / Carton Box	45308
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/ Carton Box	52647
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials / Plastic Pack	52647

Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature.	MRXDO10F.11 21.10.2013
	09 <sup>th</sup> october 2017	26 <sup>th</sup> May 2025	Amani Al-habahbeh (RA Manager)		

8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)),3x10ml/Plastic Pack	45308
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Carton Box.	45308
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml /Plastic Pack	45308
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack	45308
8.02.49.0.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/64)), 4x10ml/Carton Box	45308
8.02.49.2.0040	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-AB (1/256), Anti-D (1/128)), 4 x 10ml, 4 vials/Plastic Pack	45308
8.02.53.0.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml/Plastic Pack	45308
8.02.53.1.0040	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-AB (1/512) Anti-D (1/128)), 4x10ml, 4vials/Plastic Pack	45308
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box	52532
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1/1024) , 10 ml/vial ,1Vial/ Carton Box	52538
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1/1024) , 10 ml/vial , 1Vial/ Carton Box	45308
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent , Titer 1/256, 10ml/vial, 1Vial/ Carton Box	52647



Atlas Medical GmbH	Start of CE Marking	Date of expiry	Name & Position	Signature	MRXDO10F.11 21.10.2013
	09 <sup>th</sup> october 2017	26 <sup>th</sup> May 2025	Amani Al-habahbeh (RA Manager)		

**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**

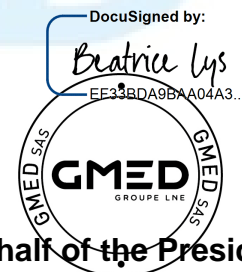


Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

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**

**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**