

CE Declaration of Conformity

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

We,
Atlas Medical

Head office: Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow
Tel: +49 - 33708 - 3550 30
Email: 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

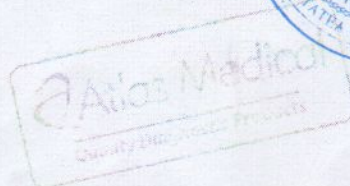
Declare our responsibility that the following product:

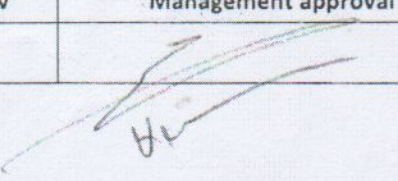
See Attached list

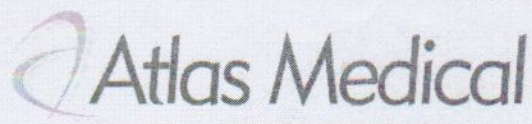
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by Lloyd's Register Quality Assurance.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



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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)

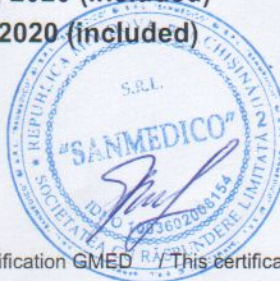
Etabli le / Issued on : March 23rd, 2020



GMED_SO_plusSites-FV0-07-2018
CERTIFICATION
DE SYSTEMES
DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

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



DocuSigned by:

On behalf of the President
Béatrice LYS
Technical Director

Béatrice LYS
BAA04A3...

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