

Declaration Ref No: DC21-0193

CE Declaration of Conformity

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

Declare our responsibility that the following product:

Product Code	Product Name	Class	GMDN code
8.00.18.0.0005	RPR Carbon Antigen Reagent, 5 ml/vial	General-IVD	32450
8.00.18.2.1000	RPR Carbon Antigen 1000ml/bottle	General-IVD	32450
8.00.18.0.0050	RPR Carbon Antigen Kit, 50 Tests	General-IVD	32450
8.00.18.1.0050	RPR Carbon Antigen Kit, 50 Tests, White Glass Slide.	General-IVD	32450
8.00.18.2.0500	RPR Carbon Antigen Kit, 500 Tests (2ml latex, 2x0.5 ml control) Without card.	General-IVD	32450
8.00.18.3.0500	RPR Carbon Antigen Kit, 500 Tests (10ml latex, 2x0.5 ml control) Without card, stirring sticks.	General-IVD	32450
8.00.18.0.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.2.0100	RPR Carbon Antigen Kit, 100 Tests (2ml latex, 2x0.5 ml control +White Glass slide stirring sticks)	General-IVD	32450
8.00.18.0.0025	RPR Carbon Antigen Kit, 25 Tests (0.5ml latex, 2x0.5 ml control)	General-IVD	32450
8.00.18.0.0150	RPR Carbon Antigen Kit, 150 Tests	General-IVD	32450
8.00.18.0.0200	RPR Carbon Antigen Kit, 200 Tests	General-IVD	32450
8.00.18.0.0250	RPR Carbon Antigen Kit, 250 Tests	General-IVD	32450

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	September.2021	06.09.2021		

Amin Al-Habashat
 RA Manager

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8.00.18.0.0500	RPR Carbon Antigen Kit,500 Tests	General-IVD	32450
8.00.18.0.1000	RPR Carbon Antigen Kit, 1000 Tests	General-IVD	32450
8.00.18.4.0500	RPR Carbon Antigen Kit,500 Tests (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.5.0500	RPR Carbon Antigen Kit, 500 Tests, (3x3.4ml reagent,2x1 controls)	General-IVD	32450
8.00.18.8.0500	RPR Carbon Antigen 500 Test (10ml reagent) without Control's.	General-IVD	32450
8.00.18.9.0050	RPR Carbon Antigen Kit, (5x10ml Reagent,2x2ml Control) , white glass Slide, Stirring Stick.	General-IVD	32450
8.33.04.0.0001	RPR Positive control	General-IVD	32450
8.33.04.1.0001	RPR Positive control ,Bulk	General-IVD	32450
8.33.04.0.0100	RPR Positive control(100ml/vial)	General-IVD	32450
8.33.04.0.0500	RPR Positive control(500ml/bottle)	General-IVD	32450
8.33.08.0.0001	RPR Negative control	General-IVD	32450

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

Certificate N^o.: 36655 rev 1

Expiry Date: October 8th.2023

and complies with the essential requirements of
In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I
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, ISO 13485:2016**

And

Intended for In-Vitro Professional use only.

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

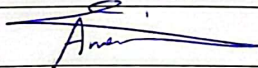
Manufacturer

Atlas Medical GmbH

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15827 Blankenefelde-Mahlow Germany.



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Amir Al-Hadad
RA Manager