

CE Declaration of Conformity

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

We,
Atlas Medical

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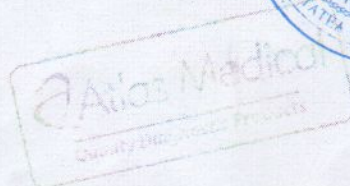
Declare our responsibility that the following product:

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		



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

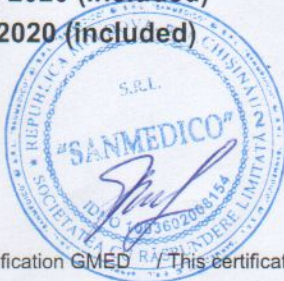
Début de validité / Effective date March 23rd, 2020 (included)

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



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

GMED_SQ_plusSites-FV0-07-2018

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