

## **ATTESTATION CE / EC CERTIFICATE**

**Approbation du Système Complet d'Assurance Qualité / Approval full Quality Assurance System**

**Annexe IV excluant les points 4 et 6 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro**

*Annex IV excluding sections 4 & 6 Directive 98/79/EC concerning in vitro diagnostic medical devices*

**Pour les dispositifs de la liste A IVD, un certificat CE de la conception est requis**

**For list A IVD devices, a EC design certificate is required**

**Fabricant / Manufacturer**

**ATLAS MEDICAL GmbH**

**Ludwig-Erhard-Ring 3**

**15827 Blankenfelde-Mahlow GERMANY**

**Catégorie du(des) dispositif(s) / Device(s) category**

**Annexe II liste A : Détermination des groupes sanguins : système ABO et rhésus D.**

*Annex II list A : Blood grouping determination : ABO system and rhesus D.*

Voir détails sur addendum  
See attachment for additional information

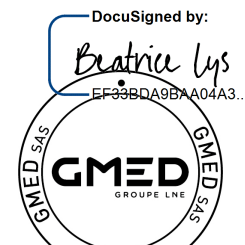
**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P601408, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe IV excluant les points 4 et 6 de la Directive 98/79/CE.**

*GMED certifies that, on the basis of the results contained in the file referenced P601408, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 98/79/EC, annex IV excluding sections 4 & 6.*

La validité du présent certificat est soumise à une vérification périodique ou imprévue  
The validity of the certificate is subject to periodic or unexpected verification

**Début de validité / Effective date : October 9th, 2020 (included)**

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



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

**Identification of devices**

**Anti-A Monoclonal Reagent, clone 9113D10**

8.02.00.0.0010	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/carton Box
8.02.00.1.0100	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 10 vials/Plastic Pack
8.02.00.1.0180	Anti-A Monoclonal Reagent (Titer: 1/512), 10ml/vial. 18 vials/carton Box

8.02.04.0.0010	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1 Vial/carton Box
8.02.04.0.0100	Anti-A Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials/Plastic Pack

8.02.70.0.0010	Anti-A monoclonal reagent, Titer (1/1024), 10 ml/vial, 1Vial/carton Box
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**Anti-B Monoclonal Reagent, clone 9621A8**

8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/carton Box
8.02.01.1.0100	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack
8.02.01.1.0180	Anti-B Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/carton Box

8.02.05.0.0010	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/carton Box
8.02.05.0.0100	Anti-B Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials/Plastic Pack

8.02.71.0.0010	Anti-B Monoclonal Reagent (Titer: 1/1024), 10 ml/vial, 1 vial/carton Box
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**Anti-AB Monoclonal Reagent, clones 152D12 + 9113D10**

8.02.02.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 1 vial/carton Box
8.02.02.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 10 vials/Plastic Pack
8.02.02.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/512), 10ml/vial, 18 vials/carton Box

8.02.06.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 1vial/carton Box
8.02.06.1.0100	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 10 vials/Plastic Pack
8.02.06.1.0180	Anti-AB Monoclonal Reagent (Titer: 1/256), 10ml/vial, 18 vials/carton Box

8.02.72.0.0010	Anti-AB Monoclonal Reagent (Titer: 1/1024), 10 ml/vial, 1Vial/carton Box
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DocuSigned by:

*Beatrice Lys*

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

**Anti-D IgG/IgM Monoclonal Reagent, clones P3X61 + P3X21223B10 + P3X290 + P3X35**

8.02.03.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 1 vial/carton Box
8.02.03.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 10 vials/Plastic Pack
8.02.03.1.0180	Anti-D IgG/IgM Blend Reagent (Titer: 1/128), 10ml/vial, 18 vials/carton Box
8.02.07.0.0010	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 1Vial/carton Box
8.02.07.1.0100	Anti-D IgG/IgM Blend Reagent (Titer: 1/64), 10ml/vial, 10 vials/Plastic Pack
8.02.85.0.0010	Anti-D IgG/IgM Blend Reagent (Titer 1/256), 10ml/vial, 1Vial/carton Box

**ABO set**

8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml/plastic Pack
8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml/Plastic Pack
8.02.47.0.0030	ABO Set (Anti-A (1/512), Anti-B (1/512), Anti-D (1/128)), 3x10ml/Plastic Pack
8.02.47.1.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml/carton Box.
8.02.47.3.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml/ Plastic Pack
8.02.47.5.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/128)), 3x10ml/Plastic Pack
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
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
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
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

**The contract concerns the following sites and activities**

- ✚ **Sahab Industrial Zone Area, king Abdullah II Industrial City, Amman 11512, JORDAN:**  
 Conception, fabrication et contrôle final / *Design, manufacture and final control*
- ✚ **Ludwig-Erhard-Ring 3 - 15827 Blankenfelde-Mahlow - GERMANY:**  
 Siège social, responsable de la mise sur le marché / *Headquarter, legal manufacturer*

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*Beatrice Lys*

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