ATTESTATION/ *CERTIFICATE* **N° 33544 rev. 3**

Délivrée à Paris le 13 mai 2022

Issued in Paris on May 13th, 2022

ATTESTATION CE / *EC CERTIFICATE*

Examen CE de la Conception (du produit) */ EC Design Examination (of the product)*

ANNEXE IV point 4 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro

ANNEX IV section 4 DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant */ Manufacturer*

ATLAS MEDICAL GmbH

Ludwig-Erhard-Ring 3

15827 Blankenfelde-Mahlow GERMANY

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

Développement, production, et commercialisation de dispositifs médicaux destinés au diagnostic in vitro.
Annexe II liste A : détermination des groupes sanguins.

Design, production and sales of medical devices for in vitro diagnostic.
Annex II list A : blood grouping determination.

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Identification du(des) dispositif(s) */ Identification of device(s)*

ATLAS Anti-A, Anti-B, Anti-AB, Anti-D Monoclonal Reagents

Voir document complémentaire GMED / See GMED additional document

n° 39002

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P605192, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P605192, the product(s) complie(s) with the requirements of the directive 98/79/EC, annex 1.

Début de validité */ Effective date :* **May 13th, 2022 (included)**

Valable jusqu'au */ Expiry date :* **May 26th, 2025 (included)**

Digitally signed by Monastîrschii Viorica
Date: 2022.12.18 14:56:34 EET
Reason: MoldSign Signature
Location: Moldova

DocuSigned by:
Beatrice Lys
EF33BDA9BAA94A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_c4p4-F-new2021-V0-09-

GMED - 33544 rev. 3
Renouvelle le certificat 33544-2

Délivré à Paris le 13/05/2022
Issued in Paris on 05/13/2022

Ce document complémentaire GMED n° 39002 rev. 0 atteste de la validité du certificat CE n° 33544 rev. 3 au regard des informations listées ci-dessous.

This GMED additional document n° 39002 rev. 0 attests to the validity of CE certificate n° 33544 rev. 3 with regard to the information listed below.

Fabricant / *Manufacturer:* **ATLAS MEDICAL GmbH**
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

Identification des dispositifs / *Identification of devices*

Annexe II liste A : détermination des groupes sanguins.
Annex II list A: blood grouping determination.

Anti-A Monoclonal Reagent, clone 9113D10
GMDN Code 52532

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

GMED	0459

GMED -39002 rev.0

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

Anti-B Monoclonal Reagent, clone 9621A8
GMDN Code 52538

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

Anti-AB Monoclonal Reagent, clones 152D12 + 9113D10
GMDN Code 46442

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

GMED	0459

GMED -39002 rev.0

DocuSigned by:
Beatrice Lys
[illegible]

On behalf of the President
Béatrice LYS
Technical Director

Anti-D IgG/IgM Monoclonal Reagent, clones P3X61 + P3X21223B10 + P3X290 + P3X35
GMDN Code 52647

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
GMDN Code 45308

8.02.05.6.0030	ABO Set (Anti-A (1/256), Anti-B (1/256), Anti-D (1/64)), 3x10ml/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

ABO set
GMDN Code 52695

8.02.05.7.0020	ABO Set: Anti-A (1/256), Anti-B (1/256), 2x10ml/Plastic Pack

GMED 0459

GMED -39002 rev.0

DocuSigned by:
Beatrice Lys

On behalf of the President
Béatrice LYS
Technical Director

ATTESTATION / *CERTIFICATE* **N° 33540 rev. 4**

Délivrée à Paris le 19 mai 2022

Issued in Paris on May 19th, 2022

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 document complémentaire GMED / See GMED additional document

n° 39019

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P601408 - P605890, 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 - P605890, the quality system - for design, manufacturing, and final inspection - of medical devices listed here aboved 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 :* **May 19th, 2022 (included)**

Valable jusqu'au */ Expiry date :* **May 26th, 2025 (included)**

DocuSigned by:
Beatrice Lys
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GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_c4-F-new2021-V0-09-

GMED 33540 rev. 4
Renouvelle le certificat 33540-3

Ce document complémentaire GMED n° 39019 rev. 0 atteste de la validité du certificat CE n° 33540 rev. 4 au regard des informations listées ci-dessous.

This GMED additional document n° 39019 rev. 0 attests to the validity of CE certificate n° 33540 rev. 4 with regard to the information listed below.

Fabricant / *Manufacturer:*

ATLAS MEDICAL GmbH
Ludwig-Erhard-Ring 3
15827 Blankenfelde-Mahlow
GERMANY

Identification des dispositifs / *Identification of devices*

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.

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

GMED 0459

GMED -39019 rev.0

DocuSigned by:
Beatrice Lys

On behalf of the President
Béatrice LYS
Technical Director

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

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

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

GMED	0459

GMED -39019 rev.0

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

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

Sites couverts et Activités / *Locations 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*

GMED	0459

GMED -39019 rev.0

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

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

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	CE	0459

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
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)	Amani	

Atlas Medical

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

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
	09th october 2017	26th May 2025	Amani Al-habahbeh (RA Manager)		

Atlas Medical
Quality Diagnostic Products

Atlas Medical

Declaration Ref No: DC22-0015

Date : 13.05.2022

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
Quality Diagnostic Products

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

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 36655 rev.1

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**

DocuSigned by:
Beatrice Lys
EE33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur 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

GMED_SQ_plus3sites-F-V0-07-2018

Addendum au certificat n° 36655 rev. 1 page 1/1
Addendum of the certificate n° 36655 rev. 1
Dossier / *File* N°P601408

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

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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

Atlas Medical

Date: 15/Jan/2022

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

Atlas Medical
Quality Diagnostic Products

Atlas Blood Grouping Reagents

Product Range:

- Anti-A, Anti-B, Anti-AB Monoclonal.
- Anti-D IgG & IgM blend.
- Anti-Human Globulin (AHG) poly-specific.
- Bovine Albumin 22% & 30%.
- Other rare antisera.

All reagents are also available in bulk OEM/private label format.

Atlas Medical

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Atlas Medical CE 0459

Blood Grouping Reagents: Anti-A Monoclonal Reagent, Anti-B Monoclonal Reagent, Anti-AB Monoclonal Reagent, Anti-D IgG/IgM blend Reagent, & Their variants SLIDE AND TUBE TESTS

IVD **For *In-Vitro* and professional use only**

Store at 2- 8°C

INTENDED USE

The blood grouping reagents are used to detect the presence or absence of A, B or Rhesus Antigens on the surface of human red blood cells based on hemaglutination using slide or tube test techniques in whole blood samples or anticoagulant blood samples collected in EDTA , citrate or heparin tubes.

INTRODUCTION & PRINCIPLES

Blood grouping reagents are prepared from In-Vitro culture supernatants of hybridized immunoglobulin-secreting mouse cell lines. The reagents are diluted with phosphate buffer containing sodium chloride, EDTA and bovine albumin to give reagents that are optimized for use in tube and slide procedures. **Anti-A monoclonal reagent is colored with acid blue (patent blue) dye, Anti-B monoclonal reagent is colored with acid yellow (tartrazine) dye, and Anti-AB monoclonal reagent is not colored.** The test procedure is based on hemaglutination principle, where red cells possessing the antigen agglutinate in the presence of the corresponding antibody indicating that the result is positive. The test is considered negative when no agglutination appears.

Anti-D IgG/IgM blend reagent is prepared from carefully blended human monoclonal IgM and IgG. Anti-D IgG/IgM blend reagent is suitable for slide and tube test procedures. The reagent will directly agglutinate Rh D positive cells, including majority of variants (but not D^{VI}) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D^{VI} and low grade weak D (D^{u}) phenotypes by the indirect anti-globulin techniques.

Anti-D IgG/IgM blend reagent is diluted with a sodium chloride solution, sodium phosphate solution and bovine albumin (sodium caprylate free). Anti-D IgG/IgM blend reagent is not colored. The procedure is based on hemaglutination principle, where red cells' possessing the antigen agglutinates in the presence of the corresponding antibody in the reagent indicating that the result is positive. The test is considered negative when no agglutination appears.

MATERIALS

MATERIALS PROVIDED

Blood Grouping Reagents:

- Anti-A monoclonal reagent (10 ml/vial), Clone: (9113D10).
- Anti-B monoclonal reagent (10 ml/vial), Clone: (9621A8).
- Anti-AB monoclonal reagent (10ml/vial), Clone: (152D12+9113D10).
- Anti-D IgG/IgM Blend reagent (10 ml/vial), Clone: (P3X61 + P3X21223B10 + P3X290 + P3X35).

MATERIALS NEEDED BUT NOT PROVIDED

- Plastic test tube or glass.
- Isotonic saline solution (% 0.9) NaCl).
- Applicator sticks.
- Centrifuge (100-1200 (g) for tube test).
- Timer.
- Incubator
- Anti-Human Globulin Reagent (can be ordered from Atlas Medical).
- White or transparent glass slide.

PRECAUTIONS

- The reagents are intended for in vitro diagnostic use only.
- The test is for well trained professional healthy user not for lay user.
- These reagents are derived from animal and human sources, thus, appropriate care must be taken in the use and disposal of these reagents, as there are no known test methods that can guarantee absence of infectious agents.
- Do not use reagents if it is turbid or contain particles as this may indicate reagent deterioration or contamination.
- Protective clothing should be worn when handling the reagents.
- **The reagents contain (0.1-0.2%) Sodium Azide and 0.02% sodium arseniate which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.**
- The reagents should be used as supplied and in accordance to the procedure mentioned below. Don't use beyond expiration date.
- Avoid cross contamination of reagents or specimens.
- Visible signs of microbial growth in any reagent may indicate degradation and the use of such reagent should be discontinued.
- Don't use these reagents if the label is not available or damaged.
- Do not use dark glass slide.
- Don't use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Wash hands and the test table top with water and soap once the testing is done.
- Heamolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well let area with very good visibility.
- Failure to follow the procedure in this package insert may give false results or safety hazard.
- Close the vial tightly after each test.
- The reagent is considered toxic, so don't drink or eat beside it.
- If spillage of reagent occurs clean with disinfectant (disinfectant used could be irritable so handle with care).

STORAGE CONDITIONS

- The reagents should be stored refrigerated between 2 - 8°C.
- Never Freeze or expose to elevated temperature.
- The reagent is stable until the expiry date stated on the product label. Do not use the reagents past the expiry date.

REAGENT PREPRATION

- The reagents are intended for use as supplied, no prior preparation or dilution of the reagent is required.
- All reagents should be brought to room temperature before use.

SPECIMEN COLLECTION AND PREPARATION

- Blood collected with or without anticoagulant (EDTA, Heparin or Citrate) can be used for Antigen typing.

Note: Blood collected without anticoagulant should be tested immediately.

- The specimens should be tested as soon as possible after collection. If testing is delayed, the specimens should be stored at 2- 8 ºC, Sample must be retained to room temperature prior to analysis. (Testing should be carried out within five days of collections).
- Insure that there is no sign of hemolysis.
- At the time of the test, centrifuge the blood sample at 1200 RCF for 3 minutes.
- Blood collection is to be done with great care.

PROCEDURES

A. DIRECT TUBE METHOD AT ROOM TEMPERATURE

1. Prepare a 5% suspension of red blood cells in isotonic solution.
2. Using the vial dropper, transfer a drop (40±10µl) of each reagent into a separate and appropriately marked tube.
3. Add 50 µl of red blood cell suspension prepared in step 1.
4. Shake to homogenize the mixture, then centrifuge at 500g for **1 minute.**
5. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
6. Read the reaction immediately.
7. For Anti-D tube, if the reaction is weak or negative, shake the tubes and incubate at 37°C for **15 minutes.**
8. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
9. Add one drop (50µl) of the AHG reagent into the tube. Mix and centrifuge at 120g for **1 minute.**
10. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
11. Read the reaction immediately.

B. ANTIGLOBULIN INDIRECT METHOD for ANTI-D

1. After immediately centrifuging and reading as above, if the reaction is weak or negative, shake the tubes and incubate at 37°C for 15 minutes.
2. Wash the red blood cells twice with isotonic saline solution (NaCl 0.9%) and discard the last washing liquid.
3. Add one drop (40 µl ± 10 µl) of ANTI-HUMAN GLOBULIN to the tube. Mix and centrifuge at 120 (g) for **1 minute**.
4. Gently shake the tube in such a way to detach the cell pellet and macroscopically observe for any possible agglutination.
5. Read the reaction immediately.

C. DIRECT SLIDE METHOD AT ROOM TEMPERATURE

1. Bring reagents and samples to room temperature (18-25°C).
2. Using the wax pen divide the slide into appropriate numbers of divisions.
3. Using the provided dropper, place one drop (40 µl ± 10 µl) of each reagent onto its correspondent division on the slide.
4. Add 25µl of the precipitated cells next to each drop of reagents.
5. Mix the reagent and the cells using a clean stirring stick over an area with a diameter of approximately 20-40mm.
6. Incubate the slide at room temperature (18-25°C) without stirring for **30 seconds**.
7. Hold the slide and gently rock the slide for **3 minutes** and observe macroscopically for any agglutination.
8. Read the reaction immediately.

READING THE RESULT

POSITIVE: If Agglutination appears.

NEGATIVE: If no agglutination is observed.

Use the below table to determine the blood group:

Result of each reaction				ABO Group
Anti-A monoclonal reagent	Anti-B monoclonal reagent	Anti-AB monoclonal reagent	Anti-D IgG/IgM blend reagent	
+	-	+	+	**A+**
+	-	+	-	**A-**
-	+	+	+	**B+**
-	+	+	-	**B-**
+	+	+	+	**AB+**
+	+	+	-	**AB-**
-	-	-	+	**O+**
-	-	-	-	**O-**

STABILITY OF THE REACTIONS

- ABO Blood Grouping Tube tests should be read immediately following centrifugation.
- Slide tests should be interpreted within three minutes to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of reagents.
- Delay in reading and interpreting results may result in weekly positive or falsely negative reactions. Slide tests should be interpreted at the end of the three minutes.

PROCEDURE LIMITATION

1. False positive/ negative results may occur due to:
   - Contamination from test materials.
   - Improper storage, cells concentration, incubation time or temperature.
   - Improper or excessive centrifugation.
   - Deviation from the recommended technique.
   - Blood samples of weak A or B subgroups may give rise to false negative results or weak reactions when tested using slide test method. It is advisable to re-test weak subgroups using tube test method.
2. Weaker reactions may be observed with stored blood than with fresh blood.
3. ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
4. ABO blood grouping interpretation on individuals greater than 6 months old should be confirmed by testing serum or plasma of the individual against group A and group B red cells (reverse grouping). If the results obtained with the serum do not correlate with the red cell test, further investigation is required.
5. Return the kit to the agent if it does not function properly.
6. Anti-D IgG/IgM blend Reagent tests conducted on particular weak-D phenotypes, while satisfactory, cannot ensure recognition of all weak variants, due to the variability of antigen patterns.

DIAGNOSTIC PERFORMANCE CHARACTERISTICS

The following tables compare the results in slide and tube techniques of 3 lots of Atlas Medical reagents and the results of a CE marked device.

Slide Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
232	232	232	232	100%
Tube Technique				
Group A				
Positive with anti-A monoclonal reagent and anti-AB monoclonal reagent Negative with anti-B and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
212	212	212	212	100%

Slide Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%
Tube Technique				
Group B				
Positive with anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with anti-A and Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
61	61	61	61	100%

Slide Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
241	241	241	241	100%
Tube Technique				
Group O				
Negative with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
243	243	243	243	100%

Slide Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
33	33	33	33	100%
Tube Technique				
Group AB				
Positive with anti-A monoclonal reagent, Anti-B monoclonal reagent and anti-AB monoclonal reagent Negative with Negative control				
CE marked device	Lot A	Lot B	Lot C	Compliance
24	24	24	24	100%

No inversion in diagnosis has been shown: from a qualitative point of view we have observed 100% compliance in direct group testing in slide and tube techniques for determination of A, B, AB and O groups for the three lots of Atlas Medical.

QUALITY CONTROL

The reactivity of all blood grouping reagents should be confirmed by testing known positive and negative red blood cells on each day of use.

To confirm the specificity and sensitivity, Blood grouping reagents should be tested with antigen-positive and antigen-negative red blood cells.

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4. Messeter L. et. al. Mouse monoclonal antibodies with anti-A, anti-B and anti-A,B specificities, some superior to human polyclonal ABO reagents, Vox Sang 46, 185-194, 1984
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PPI861A01
Rev.L (19.02.2022)

CE 0459

LIST OF VARIENTS:

Product Code	Product Name
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
8.02.01.0.0010	Anti-B Monoclonal Reagent (Titer: 1 /512), 10ml/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
8.02.02.0.0010	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
8.02.03.0.0010	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
8.02.04.0.0010	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
8.02.05.0.0010	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
8.02.05.6.0030	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
8.02.06.0.0010	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
8.02.07.0.0010	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
8.02.47.0.0030	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
8.02.70.0.0010	Anti-A monoclonal reagent , Titer (1/1024), 10 ml/vial, 1Vial/ Carton Box
8.02.71.0.0010	Anti-B Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial ,1Vial/ Carton Box
8.02.72.0.0010	Anti-AB Monoclonal reagent (Titer: 1 /1024) , 10 ml/vial , 1Vial/ Carton Box
8.02.85.0.0010	Anti-D IgG/IgM Blend reagent (Titer 1 /256), 10ml/vial, 1Vial/ Carton Box

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry