

## 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](mailto: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	<b>CE</b>	0459
-------	-----------	------

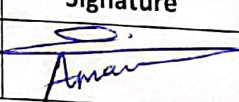
GMED, Laboratoire national de métrologie et d'essais

1 rue Gaston Boissier 75015 Paris

Tél. : 01 40 43 37 00 , TVA:FR 28 839 022 522

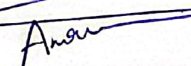
### EC Certificates No.:

- 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
	09 <sup>th</sup> october 2017	26 <sup>th</sup> May 2025	Amani Al-habahbeh (RA Manager)		




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
	09 <sup>th</sup> october 2017	26 <sup>th</sup> May 2025	Amani Al-habahbeh (RA Manager)		



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

Declaration Ref No: DC21-0035

## CE Declaration of Conformity

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

We,

### Atlas Medical

Head office: Ludwig-Erhard-Ring 3  
Blankenfelde-Mahlow, Germany.

Tel: +49 - 33708 – 3550 30

Email: [info@atlas-medical.com](mailto: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](mailto: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 GMED:  
**Certificate N°:** 36655 rev 1  
**Expiry Date:** October 8<sup>th</sup>.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And

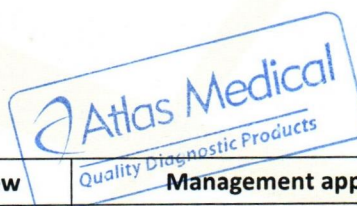
Intended for In-Vitro Professional use only.

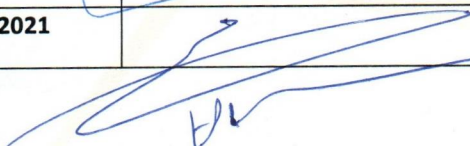
### Manufacturer

Atlas Medical

Ludwig-Erhard-Ring 3

Blankenfelde-Mahlow , Germany.



Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10
	March.2021	09.03.2021		08.02.2011



## CE Declaration of Conformity

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

Product Description
8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).
8.00.00.0.0100: CRP Latex Kit, 100 Tests (4 ml Latex, 2x1.0 ml Controls)
8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)
8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests
8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex (A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).
8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control) Without card, stirring sticks.
8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).





Mast Group Ltd.  
 Mast House  
 Derby Road  
 Bootle  
 Merseyside L20 1EA  
 United Kingdom

Tel. +44 (0)151 933 7277  
 Fax +44 (0)151 944 1332

[www.mastgrp.com](http://www.mastgrp.com)

## EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC 'on *in vitro* diagnostic medical devices', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	<b>MAST® ID identification test paper products</b> - discs, rings and strips. Products for presumptive identification of biochemical reactions or detection of a specific reaction profiles in microbes.	Self certification Annex III excluding section 6	1402020100, 1402020200, 1402020400, 1402020800, 1402029000. (codes registered - 24/03/2003)

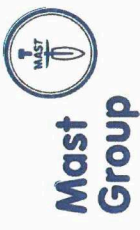
Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by .....  ..... Date: 22 March 2022

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26<sup>th</sup> May 2025





European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD  
 EC DECLARATION OF CONFORMITY - Self-Certification (Annex III excluding section 6) – General IVD

Annex – list of MAST® ID identification test paper products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	D40C	Bacitracin Discs 0.04 units	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
2	D40	Bacitracin Discs 0.04 units	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
3	D41C	Bacitracin Discs 0.1 Unit	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
4	D41	Bacitracin Discs 0.1 Unit	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
5	D42C	Optochin Discs 5ug	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
6	D42	Optochin Discs 5ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
7	D43C	X Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
8	D43	X Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
9	D44C	V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
10	D44	V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
11	D45C	X+V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
12	D45	X+V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
13	D46C	Metronidazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
14	D46	Metronidazole Discs 50ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
15	D47C	Sulphathiazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
16	D47	Sulphathiazole Discs 1ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
17	D48	Lysostaphin Discs 20ug	50 Discs	MASTDISCS® ID	For presumptive Identification of Staphylococci/micrococci.
18	D49	ALA Discs 75ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
19	D51C	Nitrate Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in anaerobes.
20	D52C	Extended Spectrum β Lactamase Set	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
21	D55	SPS Discs 1000ug	100 Discs	MASTDISCS® ID	For presumptive Identification of P. anaerobius
22	D57C	Oxidase Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in Pseudomonas spp.
23	D57	Oxidase Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Pseudomonas spp.
24	D59	Nitrocefin Discs (B)	50 Discs	MASTDISCS® ID	For presumptive Identification of Beta lactamase activity.
25	D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
26	D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.in Enterobacteriales.
27	D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
28	D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.





Serial No.	Device ID	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
29	D67C	Extended Spectrum $\beta$ Lactamase Set (CPD10)	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
30	D68C	AmpC & ESBL Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
31	D69C	AmpC Detection Set	3 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
32	D70C	Carbapenemase Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
33	D71C	CAT ID - Carbapenemase Activity Test (CAT) discs	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
34	D72C	MastDiscs® Combi AmpC, ES $\beta$ L and Carbapenemase Detection Disc Set	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
35	D73C	Carba Plus. For the detection of carbapenemase and OXA-48 enzyme production in Enterobacteriaceae.	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
36	D74	MastDiscs® ID Indirect Carbapenemase Test (ICT)	25 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
37	D76C	MastDiscs® Combi ESBL Detection Set	50 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
38	STOX	Oxacillin Strips	50 Strips	MAST® ID	Oxacillin Strips for the detection of MRSA- Antibiotic Susceptibility Testing.
39	ETO/1	MAST® ID Intralactam Strips	25 strips	MAST® ID	A strip test for the rapid detection of $\beta$ -lactamase.
40	ETO4	MAST® ID Oxidase Strips - for the performance of the oxidase reaction	25 strips	MAST® ID	A strip test for the rapid detection of cytochrome oxidase enzyme (Oxidase) in bacteria.
41	ETO7	MAST® ID PYR Strips - for the detection of pyrrolidonyl amino peptidase activity	25 strips	MAST-ID	A rapid strip test for the detection of pyrrolidonyl amino peptidase activity in streptococci and enterococci.
42	MIID/XV	MAST® ID XV Mirror ring. MASTRING™ containing X+V factor tips	50 rings	ID-MASTRING	For the identification of haemophilus spp.
43	MID8	MASTRING containing Erythromycin (60ug), Rifampicin (15ug), Colistin Sulphate (10ug), Penicillin G 2 units, Kanamycin (1000ug), Vancomycin (5ug)	50 rings	ID-MASTRING	For the presumptive identification of Gram negative non-sporing anaerobes.

Date: 05/Jan/2023

## 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, Chisinau 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: 05.01.2023

**Atlas Medical GmbH**  
Ludwig - Erhard Ring 3  
15827 Blankenfelde - Mahlow  
Tel. (0049) 33708 - 355030

**Atlas Medical:** Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Berlin, Germany,  
Tel:+4933708355030

**Regulatory Office:** William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom  
Tel: +44 (0) 1223 858 910

**Middle East Site:** P.O Box 204, King Abdullah II Industrial Estate, Amman, 11512, Jordan  
Tel: +962 6 4026468



Declaration Ref No: DC22-0065

## CE Declaration of Conformity

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

We,

### Atlas Medical GmbH

Head office: Ludwig-Erhard-Ring 3  
Blankenfelde-Mahlow, Germany.

Tel: +49 - 33708 – 3550 30

Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Manufacturing Site: Sahab Free Zone Area, P. O. Box 204, Amman 11512, Jordan.

Tel.: +962 6 4026468

Fax: +962 6 4022588

Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)

Declare our responsibility that the following product:

### See Attached list

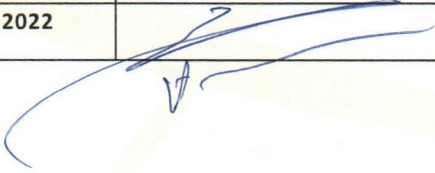
- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED:  
**Certificate N<sup>o</sup>.**: 36655 rev 1  
**Expiry Date:** October 8<sup>th</sup>.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2019, 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**  
**Blankenfelde-Mahlow , Germany.**



Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	May.2022	21.05.2022		

# CE Declaration of Conformity

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

Item code	Product Description
8.00.01.0.0100	Atlas CRP Latex Kit with Buffer (100 Tests)
8.00.05.0.0100	Atlas RF Latex kit with Buffer(100 Tests)
8.00.11.0.0050	Atlas SLE Latex kit (50 Tests)
8.00.11.0.0100	Atlas SLE Latex kit (100 Tests)
8.00.12.0.0100	Atlas Staphylococcus Latex Kit (100 Tests)
8.00.17.0.0050	Atlas D-Dimer Latex Kit (50 Tests)
8.00.19.3.0100	Atlas TPHA Kit (100 Tests)
8.00.19.3.0200	Atlas TPHA Kit (200 Tests)
8.00.20.3.2500	Atlas VDRL Kit, 5ml+55ml buffer
8.04.38.0.0020	Atlas Fecal Occult Blood Test (FOB) Test Cassette , 20 Tests/Box
8.04.85.0.0050	Atlas Fecal Occult Blood Test (FOB) Test Strip, 50 Tests/Box
8.04.109.0.0020	Atlas Procalcitonin test (PCT) , 20 Tests/Box
8.16.78.0.0025	Atlas Calprotectin Test Cassette , 25 Tests/Box
8.04.45.0.0001	Atlas Troponin I Test Cassette, Bulk
8.04.45.0.0020	Atlas Troponin I Test Cassette , 20 Tests/Box.
8.04.45.0.0030	Atlas Troponin I Test Cassette , 30 Tests/Box.
8.04.46.0.0001	Atlas Myoglobin Test Cassette, Bulk
8.04.46.0.0020	Atlas Myoglobin Test Cassette , 20 Tests/Box.
8.04.46.0.0030	Atlas Myoglobin Test Cassette , 30 Tests/Box.
8.04.47.0.0001	Atlas CK-MB Test Cassette , Bulk.
8.04.47.0.0020	Atlas CK-MB Test Cassette , 20 Tests/Box.
8.04.47.0.0030	Atlas CK-MB Test Cassette , 30 Tests/Box.
8.04.48.0.0001	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), Bulk.
8.04.48.0.0020	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 20 Tests/Box.
8.04.48.0.0030	Atlas Cardiac Triple Tests Cassette (Troponin I, CK-MB, Myoglobin), 30 Tests/Box.
8.14.19.1.0096	Helicobacter pylori Antigen ELISA, 96 Tests.
8.51.00.0.0096	25-OH VITAMIN D Elisa Kit, 96 Tests.
8.57.00.0.0096	Vitamin B12 Elisa Kit, 96 Tests





**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**

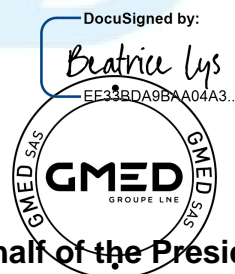


**CERTIFICATION DE SYSTEMES DE MANAGEMENT**  
Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)

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



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

**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*

\*\*\*\*\*

**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**



## 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

2°C  8°C  
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 hemagglutination 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 hemagglutination 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<sup>VI</sup>) and a high proportion of weak D (Du) phenotypes. The reagent will agglutinate category D<sup>VI</sup> and low grade weak D (D<sup>VI</sup>) 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 hemagglutination 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.
- Hemolysed blood sample should not be used for testing.
- The test should be performed at room temperature in a well lit 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 PREPARATION

- 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 °C. 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**

- 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.
- Weaker reactions may be observed with stored blood than with fresh blood.
- ABO antigens are not fully developed at birth, weaker reactions may therefore occur with cord or neonatal red cells.
- 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.
- Return the kit to the agent if it does not function properly.
- 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.

**REFERENCES**

1. BCSH Blood Transfusion Task Force. Guidelines for microplate techniques in liquid-phase blood grouping and antibody screening. Clin. Lab. Haem 1990; 12, 437-460.
2. Issitt P. D. Applied Blood Group Serology, 3rd ed. Miami: Montgomery Scientific, 1985.
3. Kholer G., Milstein C. Continuous culture of fused cells secreting antibody of predefined specificity, 256, 495-497, 1975
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
5. Race R.R. and Sanger R. Blood groups in man, 6th ed., Oxford: Blackwell Scientific, 1975.
6. Voak D. ET. al., Monoclonal anti-A and anti-B development as cost effective reagents. Med. Lab. Sci 39, 109-122. 1982.



7. Standards for Blood Banks and Transfusion Service. 11th Ed., Washington D.C., AABB 1984:25.

8. Widmann F.K.ed Technical Manual, 9th Ed., Washington D.C.: AABB 1985:9.



Atlas Medical GmbH  
Ludwig-Erhard-Ring 3  
15827 Blankenfelde-Mahlow  
Germany  
Tel: +49 - 33708 – 3550 30  
Email: [info@atlas-medical.com](mailto:info@atlas-medical.com)  
Website: [www.atlas-medical.com](http://www.atlas-medical.com)

PP1861A01  
Rev.L (19.02.2022)



LIST OF VARIANTS:

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

	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	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