EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Gilson Pipette Tips**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

Digitally signed by Ceaicovschi Tudor
Date: 2024.02.06 15:24:23 EET
Reason: MoldSign Signature
Location: Moldova

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

BOEN HEALTHCARE CO.,LTD 苏州博恩贸易有限公司 91320505311038530

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

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Name and address of the manufacturer: /
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Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

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Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Pasteur Pipette

der Klasse: /
of class: /
de la classe: /
di classe:

Common/Others IVD
(Devices of NOT Annex II and NOT self-test)

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

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soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /
EG Annex III (expect point 6) of IVDD 98/79/EC
Annexe III (sauf le point 6) de l'IVDD 98/79 / CE
Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

EC DECLARATION OF CONFORMITY

according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices

in combination with article 110 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017

We, **DRG Instruments GmbH**, Frauenbergstr. 18, 35039 Marburg, Germany

herewith declare under our own responsibility that the products listed in the table below,

which are classified as miscellaneous products under Directive 98/79/EC

are in accordance with the requirements of the IVD Directive 98/79/EC annex I and III of the European Parliament in regard to the in vitro diagnostic medical devices (IVDs) and therefore are allowed to be CE marked.

Quality Management

DRG Instruments GmbH has established a Quality Management System for the design/development, production and distribution of in vitro diagnostic according to **EN ISO 13485:2016**.

Disclaimer

This Declaration of Conformity was created after the Date of Application of IVDR (May 26th, 2022). However, the cause for the creation of this Declaration of Conformity is NOT considered a "significant change" according to IVDR in combination with MDCG 2022-6 and therefore, the device continues to comply to IVDD.

Marburg, 2023-10-23

Dr. Matthias Herkert
PRRC

Product Name	*DRG Cat.-No*
FSH ELISA	EIA-1288
LH-Serum ELISA	EIA-1289
Prolactin ELISA	EIA-1291
17-OH Progesterone ELISA	EIA-1292
C-Peptide ELISA	EIA-1293
AFP	EIA-1468
HCG ELISA	EIA-1469
Testosterone ELISA	EIA-1559
Progesterone ELISA	EIA-1561

DRG Instruments GmbH
Geschäftsführer:
Jörg Schlösser
Sitz: Marburg, HRB 1165

DRG

EC DECLARATION OF CONFORMITY

according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices

Product Name	*DRG Cat.-No*
DHEA-S ELISA	EIA-1562
Free Estriol ELISA	EIA-1612
Immunoglobulin E (IgE) ELISA	EIA-1788
Sperm Antibody ELISA	EIA-1826
TGF-ß1 ELISA	EIA-1864
CEA ELISA	EIA-1868
Cortisol ELISA	EIA-1887
Anti-GAD ELISA	EIA-1910
ß-HCG ELISA	EIA-1911
Helicobacter pylori IgM ELISA	EIA-2111
TGF-ß2 ELISA	EIA-2396
Estradiol ELISA	EIA-2693
Free Testosterone ELISA	EIA-2924
Insulin ELISA	EIA-2935
SHBG ELISA	EIA-2996
CIC C1q ELISA	EIA-3169
Androstenedione ELISA, 96 well	EIA-3265
Osteocalcin ELISA	EIA-3375
Thyroglobulin ELISA	EIA-3377
Adenovirus IgA ELISA	EIA-3445
Adenovirus IgG ELISA	EIA-3446
Adenovirus IgM ELISA	EIA-3447
Bordetella pertussis IgA ELISA, 96 well	EIA-3449
Bordetella pertussis IgG ELISA	EIA-3450
Bordetella pertussis IgM ELISA	EIA-3451
Brucella IgG ELISA, 96 Well	EIA-3455
Brucella IgM ELISA	EIA-3456
Candida albicans IgA ELISA	EIA-3457
Candida albicans IgG ELISA	EIA-3458
Candida albicans IgM ELISA	EIA-3459
Giardia lamblia Ag (stool) ELISA,	EIA-3477
Helicobacter pylori IgA ELISA	EIA-3483
Helicobacter pylori IgG ELISA	EIA-3484
HSV-1 IgG ELISA	EIA-3485

DRG

EC DECLARATION OF CONFORMITY

according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices

Product Name	*DRG Cat.-No*
HSV-1 IgM ELISA	EIA-3486
HSV-2 IgG ELISA	EIA-3487
HSV-2 IgM ELISA	EIA-3488
HSV-1+2 IgG ELISA, 96 well	EIA-3489
HSV-1+2 IgM ELISA	EIA-3490
Mycoplasma pneumoniae IgG ELISA	EIA-3499
Mycoplasma pneumoniae IgM ELISA	EIA-3500
Tetanus toxin IgG ELISA	EIA-3514
Treponema pallidum IgG ELISA	EIA-3517
hGH ELISA	EIA-3552
Anti TPO Ab ELISA	EIA-3561
Anti-Centromere B ELISA	EIA-3569
Anti-Cardiolipin IgG/IgM ELISA	EIA-3587
Anti-Phospholipid Screen IgG/IgM ELISA, 96 well	EIA-3591
Anti-Gliadin IgG ELISA, 96 well	EIA-3605
Anti-Gliadin IgA ELISA	EIA-3606
Anti-Insulin ELISA	EIA-3608
Anti-Tissue-Transglutaminase IgA ELISA	EIA-3611
ACTH (Adrenocorticotropic Hormone) ELISA	EIA-3647
Calcitonin	EIA-3648
Anti TG Ab ELISA	EIA-3708
Free T4 ELISA	EIA-3775
Free T3 ELISA	EIA-3801
Measles Virus IgG ELISA	EIA-3844
Measles Virus IgM ELISA	EIA-3845
Mumps Virus IgG ELISA	EIA-3846
Mumps Virus IgM ELISA	EIA-3847
Mycoplasma pneumoniae IgA ELISA	EIA-3848
Anti-Tissue-Transglutaminase IgG ELISA	EIA-3882
Histamine ELISA	EIA-4005
TSH ELISA	EIA-4171
EBV-EBNA-1 IgG ELISA (qualitative)	EIA-4246
EBV-EBNA-1 IgM ELISA (qualitative)	EIA-4247
Treponema pallidum IgM ELISA	EIA-4267

EC DECLARATION OF CONFORMITY

according to Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices

Product Name	*DRG Cat.-No*
Ferritin ELISA	EIA-4408
EBV VCA IgA ELISA (qualitative)	EIA-4472
PLGF ELISA	EIA-4529
Mycoplasma hominis IgG ELISA	EIA-4559
Mycoplasma hominis IgM ELISA	EIA-4560
Ureaplasma urealyticum IgM ELISA	EIA-4561
T4 Total ELISA	EIA-4568
T3 Total ELISA	EIA-4569
NSE ELISA	EIA-4610
Ureaplasma urealyticum IgG ELISA	EIA-4623
TM-CA 15-3 ELISA	EIA-5068
TM-CA 19-9 ELISA	EIA-5069
TM-CYFRA 21-1 ELISA	EIA-5070
TM-CA 72-4 ELISA	EIA-5071
TM-CA 125 ELISA	EIA-5072
Mycoplasma hominis IgA ELISA	EIA-5097
Ureaplasma urealyticum IgA ELISA	EIA-5098
Calprotectin (Serum) ELISA	EIA-5111
Procalcitonin (Human) ELISA	EIA-5291
Aldosterone ELISA	EIA-5298
Anti-CCP ELISA	EIA-5653
Anti-C1q ELISA	EIA-5762
Strongyloides IgG/IgM ELISA	EIA-5812
Folic Acid ELISA	EIA-5847
Hanta Virus IgG ELISA	EIA-5858
Hanta Virus IgM ELISA	EIA-5859
Aspergillus fumigatus IgG ELISA	EIA-6129
Aspergillus fumigatus IgM ELISA	EIA-6130
AMH (Anti-Mullerian Hormone)	EIA-6141
Estriol total ELISA	EIA-6193
EBV (EA) IgG ELISA	EIA-6203
EBV (EA) IgM ELISA	EIA-6204
end of list	

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

от 30 октября 2012 года

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
и подтверждает, что медицинское изделие
Набор реагентов "Антиген кардиолипиновый для реакции микропреципитации "Сифилис-АгКЛ-РМП"
по ТУ 9398-016-70423725-2010 в следующей комплектации
производства
Закрытое акционерное общество "ЭКОлаб", (ЗАО "ЭКОлаб"),
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1
место производства:
Россия, 142530, Московская область, г. Электрогорск, ул. Буденного, д. 1

класс потенциального риска **2б** ОКП **93 9817**

вид медицинского изделия –

соответствующее регистрационному досье № 33508 от 26.09.2012

В соответствии с приказом Росздравнадзора от 30 октября 2012 года № 2280-Пр/12 и приказом от 23 июля 2013 года № 3428-Пр/13 о замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

0001831

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2011/09957

Комплект № 1 включает в составе:
- антиген кардиолипиновый (АгКЛ);
- раствор холин-хлорида в 0,9 % растворе натрия хлорида.

Комплект № 2 в составе:
- взвесь АгКЛ.

2

Приказом от 23 июля 2013 года № 3428-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

30 октября 2012 года

0001854

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products;
AccuBind® ELISA,
AccuLite® CLIA,
QSure® Control,
Instruments
see appendix

4) The product(s) described above is in conformity with:

Document No.	Title
98/79/EC	*In vitro* Diagnostic Medical Devices Directive

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2021-09-20 — A Shatola

(Place & date of issue (yyyy-mm-dd))

Tony Shatola; QA Director, Monobind Inc.
(name, function and signature of manufacturer)

Appendix

Date: 2021-09-20

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Allergy & Anemia							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
Autoimmune							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
Bone Metabolism & Growth							
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
Diabetes							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
Endocrine							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
Fertility & Prenatal							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid -hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
Infectious Diseases							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
Neonatal							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
Steroid							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
Thyroid							
Total Triidothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triidothyronine (fT3) Test Stystem	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triidothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triidothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instru-ment	EDMS code	Risk Class	First date of CE-marking
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triidothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29
Miscellaneous Controls							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analzyer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05

Certificate of Registration of Quality Management System to ISO 13485:2016

Brazil - RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada - Medical Devices Regulations – Part 1- SOR 98/282
United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 - Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

Facility ID: F002818
has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4585)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4585 / Rev 2
Certification Granted: 2019/09/25
Effective Date: 2022/09/25
Expiry Date: 2025/09/24

Annex to Certificate Number: MP19.4585 / Rev 2

Scope of Registration:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585 Facility ID: F002818
Manufacture, Distribution	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MP19.4585/A Facility ID: F002818

Verified by:
Director of Certification

ORGENTEC

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 540A Anti-Tissue-Transglutaminase IgA

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH * ORGENTEC CE and ISO approved * Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-21-00
GMDN 55223

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540A_4

ORG 540A Anti-Tissue-Transglutaminase IgA

INTENDED PURPOSE

Anti-Tissue-Transglutaminase IgA is an ELISA test system for the quantitative measurement of IgA class autoantibodies to tissue transglutaminase (tTG) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Autoantibodies against tissue transglutaminase (tTG) during a gluten containing diet are the most obvious serologic feature of coeliac disease (CD). Determination of serum levels of IgA against tTG is the first choice in suspected CD. In subjects with either primary or secondary humoral IgA deficiency, at least one additional test measuring IgG class CD-specific antibodies is recommended. The clinical relevance of a positive anti-tTG result should be confirmed by histology of the small intestinal mucosa.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
540A_4	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Human recombinant tissue transglutaminase is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 540A	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***tTG***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 5 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 10 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 25 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 75 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate; light red, containing anti-human IgA antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µl** of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µl** of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units, since no international reference preparation is available for this assay.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 10 U/ml

Interpretation of results

Negative: < 10 U/ml
Positive: ≥ 10 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	196.9	196.9	100
.	1:200	103.9	98.5	105
.	1:400	49.0	49.2	100
.	1:800	25.2	24.6	102
.	1:1600	11.3	12.3	92
2	1:100	199.3	199.3	100
.	1:200	100.8	99.7	101
.	1:400	49.8	49.8	100
.	1:800	25.8	24.9	104
.	1:1600	11.7	12.5	94

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 8 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	0.9	10.4
2	47.1	4.4
3	112.8	8.7

Inter-Assay		
Sample	Mean U/ml	CV %
1	1.3	10.6
2	19.4	13.7
3	108.5	11.1

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Coeliac disease	35	35	100.0
Normal human sera	90	2	2.2

		Clinical Diagnosis POS	NEG	
ORG 540A	POS	35	2	
	NEG	0	88	
		35	90	125

Sensitivity: 100.0 %
Specificity: 97.8 %
Overall agreement: 98.4 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

REFERENCES

1. Alessio M, Tonutti E, Brusca I, Radice A, Licini L, Sonzogni A, Florena A, Schiaffino E, Marus W, Sulfaro S, Villalta D: Correlation between IgA tissue transglutaminase antibody ratio and histological finding in celiac disease: A multicentre study. J Pediatr. Gastroenterol. Nutr. 2011.
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9. Murray JA: Serodiagnosis of celiac disease. Clin. Lab. Med. 1997, 17:445-464.
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Notice to the user (European Union):
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control
Former version: *ORG 540A_IFU_EN_QM113174_2016-05-13_2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

EG Konformitätserklärung

EC Declaration of Conformity

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt

We declare in our sole responsibility that the ORGENTEC product

ORG 540G Anti-Tissue-Transglutaminase IgG

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte" (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) *according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.*

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewendeter Normen:

List of standards applied for CE marking:
EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

ORGENTEC Diagnostika GmbH * ORGENTEC CE and ISO-approved * Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs

Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG
Type: Reagent
EDMS 12-10-90-21-00
GMDN 55223

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540G_4

ORG 540G Anti-Tissue-Transglutaminase IgG

INTENDED PURPOSE

Anti-Tissue-Transglutaminase IgG is an ELISA test system for the quantitative measurement of IgG class autoantibodies to tissue-transglutaminase (tTG) in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

Autoantibodies against tissue transglutaminase (tTG) during a gluten containing diet are the most obvious serologic feature of coeliac disease (CD). Determination of serum levels of IgA against tTG is the first choice in suspected CD. In subjects with either primary or secondary humoral IgA deficiency, at least one additional test measuring IgG class CD-specific antibodies is recommended. The clinical relevance of a positive anti-tTG result should be confirmed by histology of the small intestinal mucosa.

SYMBOLS USED ON LABELS

IVD	In vitro diagnostic medical device
	Manufacturer
REF	Catalogue number
96	Sufficient for 96 determinations
LOT	Batch code
	Use by
2°C 8°C	Temperature limitation
	Keep away from sunlight
	Do not reuse
	Date of manufacture
CE	CE marked according to 98/79/EC
	Consult instructions for use
540G_4	Electronic Instruction For Use: version

MICROPLATE	Microplate
CALIBRATOR A	Calibrator
CALIBRATOR B	Calibrator
CALIBRATOR C	Calibrator
CALIBRATOR D	Calibrator
CALIBRATOR E	Calibrator
CALIBRATOR F	Calibrator
CONTROL +	Control positive
CONTROL −	Control negative
DILUENT	Sample Buffer P
CONJUGATE	Enzyme Conjugate
TMB	TMB Substrate
STOP	Stop solution
WASH	Wash Buffer
RTU	Ready to use

PRINCIPLE OF THE TEST

Human recombinant tissue transglutaminase is bound to microwells.
The determination is based on an indirect enzyme linked immune reaction with the following steps:
Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subesquently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stopps the reaction generating a yellow end-product. The intensity of the yellow color
correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3´,5,5´-Tetramethyl-benzidine).
- Stop solution contains acid, classifiaction is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 540G	Σ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: ***tTG***
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 U/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 5 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 10 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 25 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 75 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 U/ml, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL −	1x 1.5 ml	Control negative, containing tTG antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopended test kit is 18 months from day of production. Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C. We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, performe the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

1. Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
   Incubate for **30 minutes** at room temperature (20-28 °C).
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
2. Dispense **100 µ**l of enzyme conjugate into each well.
   Incubate for **15 minutes** at room temperature.
   Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
3. Dispense **100 µ**l of TMB substrate solution into each well.
   Incubate for **15 minutes** at room temperature
4. **Add 100 µl** of stop solution to each well of the modules
   Incubate for **5 minutes** at room temperature.
   Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
   The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.
Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

This assay system is calibrated in relative arbitrary units, since no international reference preparation is available for this assay.

Measuring range

The calculation range of this ELISA assay is 0 - 200 U/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 10 U/ml

Interpretation of results

Negative: < 10 U/ml
Positive: ≥ 10 U/ml

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed U/ml	Expected U/ml	O/E [%]
1	1:100	188.0	188.0	100
.	1:200	101.7	94.0	108
.	1:400	48.4	47.0	103
.	1:800	24.1	23.5	103
.	1:1600	10.9	11.8	93
2	1:100	196.0	196.0	100
.	1:200	97.2	98.0	99
.	1:400	49.4	49.0	101
.	1:800	24.8	24.5	101
.	1:1600	11.9	12.3	97

Limit of detection

Functional sensitivity was determined to be: 1 U/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.
Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 8 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean U/ml	CV %
1	4.2	6.5
2	20.7	6.7
3	63.7	6.1

Inter-Assay		
Sample	Mean U/ml	CV %
1	4.5	10.9
2	22.4	9.2
3	74.0	8.8

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Coeliac disease	35	23	65.7
Coeliac disease (IgA deficient)	8	8	100.0
Normal human sera	90	0	0.0

		Clinical Diagnosis POS	NEG	
ORG 540G	POS	31	0	
	NEG	12	90	
		43	90	133

Sensitivity: 72.1 %
Specificity: 100.0 %
Overall agreement: 91.0 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.
The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establishe its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Change Control
Former version: *ORG 540G_IFU_EN_QM113175_2016-05-13_2* Reason for revision: *Introduction electronic IFU on homepage*

1. Pipet **100 µl** calibrator, control or patient sample
   → Incubate for **30 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
2. Pipet **100 µl** enzyme conjugate
   → Incubate for **15 minutes** at room temperature
   → Discard the contents of the wells and wash 3 times with **300 µl** wash solution
3. Pipet **100 µl** substrate solution
   → Incubate for **15 minutes** at room temperature
4. Add **100 µl** stop solution
   → Leave untouched for **5 minutes**
   → Read at **450 nm**

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»
№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

№ 0117161

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.04ИБФ1.ОС23.0000308

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. :+7 (812) 649-93-88, email: info@essert.ru

ВЫДАН

Закрытому акционерному обществу «ЭКОлаб»
ИНН 5035025076 ОГРН 1035007106958
Адрес: 142530, РФ, Московская область, г. Электрогорск, ул. Буденного, д. 1

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА МЕДИЦИНСКИХ ИЗДЕЛИЙ

применительно к работам согласно приложению № 1 к настоящему сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.0000308П от 30.06.2022

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ПромТех Стандарт РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130.

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117162

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

РАЗРЕШЕНИЕ

НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

Регистрационный номер РОСС RU.04ИБФ1.ОС23.0000308Р

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. :+7 (812) 649-93-88, email: info@essert.ru

ВЫДАНО

Закрытому акционерному обществу «ЭКОлаб»
ИНН 5035025076 ОГРН 1035007106958
Адрес: 142530, РФ, Московская область, г. Электрогорск, ул. Буденного, д. 1

на основании сертификата № РОСС RU.04ИБФ1.ОС23.0000308

Настоящее разрешение предоставляет право применения знака соответствия системы добровольной сертификации «ПРОМТЕХСТАНДАРТ»:

при маркировке продукции, при оказании работ (услуг), на бланках организации, в рекламно-информационных материалах, печатных изданиях, вывесках, выставочных стендах и т.д., на сайтах организации в сети Интернет, в соответствии с правилами применения знака соответствия системы добровольной сертификации "ПромТехСтандарт"

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117163

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000720Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Овинникова Светлана Сергеевна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.000720ПЭ от 30.06.2022
и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" для сертификатов системы добровольной сертификации ПромТех Стандарт * РОСС RU.32001.04ИБФ1.ОС23 *

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117164

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000721Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Котляр Марина Анатольевна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.000721ПЭ от 30.06.2022
и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Руководитель органа _____ (подпись) А.В. Арендарь (инициалы, фамилия)

Председатель комиссии _____ (подпись) А.А. Акимов (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117165

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000722Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23

Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Трощенкова Елена Петровна

соответствует требованиям

предъявляемым системой добровольной сертификации "ПромТехСтандарт"

к экспертам-аудиторам внутренних проверок

системы менеджмента качества медицинских изделий

на соответствие требованиям стандарта

ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,

протокол № РОСС RU.04ИБФ1.ОС23.000722ПЭ от 30.06.2022

и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ Система добровольной сертификации ПромТех Стандарт * РОСС RU.32001.04ИБФ1.ОС25 *

Руководитель органа _____ А.В. Арендарь
подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117166

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000723Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нищакова Наталья Евгеньевна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.000723ПЭ от 30.06.2022
и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ системы добровольной сертификации ПромТех Стандарт РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ А.В. Арендарь
подпись — инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись — инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117167

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

СЕРТИФИКАТ СООТВЕТСТВИЯ ЭКСПЕРТА

Регистрационный номер РОСС RU.04ИБФ1.ОС23.000724Э

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел.: +7 (812) 649-93-88, email: info@essert.ru

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Королева Татьяна Александровна

соответствует требованиям
предъявляемым системой добровольной сертификации "ПромТехСтандарт"
к экспертам-аудиторам внутренних проверок
системы менеджмента качества медицинских изделий
на соответствие требованиям стандарта
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол № РОСС RU.04ИБФ1.ОС23.000724ПЭ от 30.06.2022
и зарегистрирован в реестре экспертов системы добровольной сертификации "ПромТехСтандарт".

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ Система добровольной сертификации ПромТех Стандарт * РОСС RU.32001.04ИБФ1.ОС23

Руководитель органа _____ А.В. Арендарь
подпись инициалы, фамилия

Председатель комиссии _____ А.А. Акимов
подпись инициалы, фамилия

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130

RUSSIAN FEDERATION

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ 0117168

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.04ИБФ1.ОС23.0000308
(является неотъемлемой частью сертификата соответствия)

Срок действия с 30.06.2022 по 29.06.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС23
Общество с ограниченной ответственностью «ЕВРАЗИЙСКИЙ СОЮЗ СЕРТИФИКАЦИИ»
192289, город Санкт-Петербург, улица Олеко Дундича, дом № 35, корпус 1, литера А, 2-Н, офис 4,
тел. : +7 (812) 649-93-88, email: info@essert.ru

Применительно к видам работ:

ОКВЭД:
46.46.2 - Торговля оптовая изделиями, применяемыми в медицинских целях

ОКВЭД 2:
21.20.2 Производство материалов, применяемых в медицинских целях
72.19 Научные исследования и разработки в области естественных и технических наук прочие
86.90.9 Деятельность в области медицины прочая, не включенная в другие группировки

Орган по сертификации ООО "Евразийский Союз Сертификации" ДЛЯ СЕРТИФИКАТОВ Системы добровольной сертификации ПромТех Станд. * РОСС RU.32001.04ИБФ1.ОС23 *

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Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2021 г., «В», ТЗ № 1130