



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG038
Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: *Shanghai International Holding Corp. GmbH (Europe)*

EC Representative's Address: *Eiffestrasse 80, 20537 Hamburg, Germany*

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: August 11, 2020

Name of authorized signatory: *Joyce Pang*
Position held in the company: *Vice-President*



Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.: SH2198802

Valid from: 2022-04-11

Valid until: 2024-03-16

Date, 2022-04-11

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product 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.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager:

Date:2023/2/21



[Handwritten signature in blue ink]

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China
电话 Tel:+86-572-5226111 传真 Fax: +86-572-5226222 邮编 P.C.:313300

Troponin I

Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.¹ Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.² After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.³ cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.⁴ Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.⁵

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal dog conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- For professional In Vitro diagnostic use only.
- Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Do not use it if the tube/pouch is damaged or broken.
- Test is for single use only. Do not re-use under any circumstances.
- Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

MATERIALS

Materials Provided

- Test devices
- Buffer

- Disposable Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)

- Clock or Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.

- Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.

OR

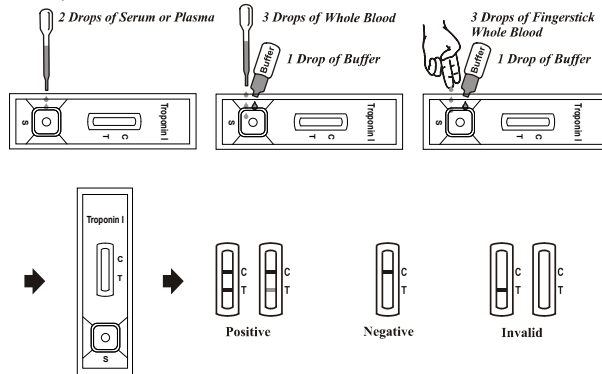
Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer.

OR

Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.

- Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method	Troponin I Rapid Test Device		Total Results
	Results	Positive	Negative
EIA	Positive	138	2
	Negative	1	315
Total Results		139	317
		456	

Relative Sensitivity: 98.6% (94.9%-99.8%)*

Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)*

*95% Confidence Interval

BIBLIOGRAPHY

- Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
- Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
- Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
- Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
- Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.



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Тел.: +38 (095) 60-99-555 Факс: +38 (044) 422-62-16
e-mail: info@xema.com.ua
www.xema.in.ua

STATEMENT

We, XEMA LLC, as a manufacturer of in vitro diagnostic medical devices, having a registered office at Akademika Yefremova St. 23, Kyiv, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with legislative requirements of the Republic of Moldova.

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.

This Statement shall come into force on the date of its signing. The duration of this Statement is 3 years from the date of signing.

Date: 06.09.2023

Signature:

Director Xema LLC
Oleksandra Zavaliei



Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. **AR/IVD/XEMA LLC/01/2023**

Issued on the basis of the Declaration of conformity and registration taking into account Article 11 of Regulation (EU) 2017/746 (IVDR) on In Vitro Diagnostic, and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der der Verordnung (EU) 2017/746 (IVDR) über In-vitro-Diagnostika und Medizinprodukte-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller

XEMA LLC

SRN: UA-MF-000032959

UKRAINE, 03179 KYIV
Akademika Yefremova St. 23
qa@xema.com.ua; www.xema.in.ua

Product name / Produkt

See annex to the Certificate
Siehe Anhang zum Zertifikat

Product Classification:
Produktklassifizierung

In Vitro Diagnostic Medical Devices
In-vitro-Diagnostikum (IVD) Medizinprodukte

Category:
Kategorie

Common/ Other IVD
Sonstige IVD-Produkte

Conformity assessment procedure:
Konformitätsbewertungsverfahren:

EC DECLARATION OF CONFORMITY
(Annex III, except point 6, Directive 98/79/EC)
in connection with article 110(3) IVDR

EU- KONFORMITÄTSEKTLARUNG
(Anhang III, außer Nummer 6, Richtlinie 98/79 / EG)
in Verbindung mit Artikel 110 (3) IVDR

State Competent Authority:
Staatliche Zuständige Behörde

BfArM Federal Institute for Drugs and Medical Devices
DMIDS (German Medical Device Information and Database System)

BfArM Das Bundesinstitut für Arzneimittel und Medizinprodukte DMIDS
(Deutsches Medizinprodukte-Informations- und Datenbanksystem)

Date of issue : **2023-03-07**
Das Ausstellungsdatum

Valid to : **2025-05-31**
Gültig bis

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 93163967



Polmed.de

SRN: DE-AR-000006947

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
1.	ASPERGILLUS	K021	GalMAg EIA	DE/CA64/00115824
2.	HSV IgG	K104	HSV 1/2 IgG EIA	DE/CA64/00115826
3.	HSV IgM	K104M	HSV 1, 2 IgM EIA	DE/CA64/00115833
4.	HSV 2 IgG	K104B	HSV 2 IgG EIA	DE/CA64/00115836
5.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA	DE/CA64/00115837
6.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	anti-Treponema pallidum EIA	DE/CA64/00115839
7.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA	DE/CA64/00115840
8.	H. PYLORI ANTIBODY ASSAYS	K119G	Helicobacter pylori IgG EIA	DE/CA64/00115850
9.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA	DE/CA64/00115851
10.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA	DE/CA64/00115852
11.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA	DE/CA64/00115853
12.	MPO ANCA	K133	aMPO EIA	DE/CA64/00115854
13.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	anti-TGlu IgG EIA anti-TGlu IgA EIA	DE/CA64/00115855
14.	GIARDIA LAMBLIA	K171	anti-Giardia lamblia EIA	DE/CA64/00115856
15.	OTHER PARASITOLOGY	K174	Ascaris IgG EIA	DE/CA64/00115857
16.	ECHINOCOCCUS	K175	Echinococcus IgG EIA	DE/CA64/00115858
17.	DISTOMATOSIS	K176	Opisthorchis IgG EIA	DE/CA64/00115859
18.	GLIADIN ANTIBODIES	K180 K181	Gliadin IgG EIA Gliadin IgA EIA	DE/CA64/00115860
19.	IMMUNOGLOBULIN E - TOTAL	K200	Total IgE EIA	DE/CA64/00115861
20.	THYROID STIMULATING HORMONE	K201	TSH EIA	DE/CA64/00115863
21.	LUTEINISING HORMONE	K202	LH EIA	DE/CA64/00115864
22.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA	DE/CA64/00115865
23.	HUMAN GROWTH HORMONE	K204	GH EIA	DE/CA64/00115866
24.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	hCG EIA	DE/CA64/00115867
25.	PROLACTIN	K206	Prolactin EIA	DE/CA64/00115868

The above-mentioned medical products are marked with the CE symbol.
 Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
26.	PROGESTERONE	K207	Progesterone EIA	DE/CA64/00115869
27.	ESTRADIOL	K208	Estradiol EIA	DE/CA64/00115870
28.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209	Testosterone EIA	DE/CA64/00115871
29.	CORTISOL	K210	Cortisol EIA	DE/CA64/00115872
30.	TRIIODOTHYRONINE	K211	T3 EIA	DE/CA64/00115873
31.	THYROXINE	K212	T4 EIA	DE/CA64/00115874
32.	FREE TRIIODOTHYRONINE	K213	ft3 EIA	DE/CA64/00115875
33.	FREE THYROXINE	K214	ft4 EIA	DE/CA64/00115876
34.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEAS EIA	DE/CA64/00115877
35.	17 OH PROGESTERONE	K217	17-OH-progesterone EIA	DE/CA64/00115878
36.	ESTRIOL	K218	free Estriol EIA	DE/CA64/00115880
37.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	free Testosterone EIA	DE/CA64/00115881
38.	CANCER ANTIGEN 125	K222	CA 125 EIA	DE/CA64/00115882
39.	CANCER ANTIGEN 19-9	K223	CA 19-9 EIA	DE/CA64/00115883
40.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA	DE/CA64/00115884
41.	ALPHAFETOPROTEIN	K225	AFP EIA	DE/CA64/00115885
42.	CANCER ANTIGEN 15-3	K226	CA 15-3 (M12) EIA	DE/CA64/00115886
43.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA	DE/CA64/00115887
44.	β HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	free β-HCG EIA	DE/CA64/00115888
45.	CYFRA 21-1	K236	CYFRA 21-1 EIA	DE/CA64/00115889
46.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC (A) EIA	DE/CA64/00115890
47.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA	DE/CA64/00115892
48.	OTHER OTHER TUMOUR MARKERS	K239	HE4 EIA	DE/CA64/00115893
49.	CANCER ANTIGEN 242	K243	CA242 EIA	DE/CA64/00115894
50.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA	DE/CA64/00115896

The above-mentioned medical products are marked with the CE symbol.
 Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

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Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
51.	HUMAN PLACENTAL LACTOGEN HPL	K246	Placental lactogen EIA	DE/CA64/00115897
52.	C-REACTIVE PROTEIN	K250	CRP EIA	DE/CA64/00115898
53.	C-PEPTIDE	K267C	C-peptide EIA	DE/CA64/00115900
54.	INSULIN	K267N	Insulin EIA	DE/CA64/00115901
55.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA	DE/CA64/00115902
56.	TROPONIN (T + I)	K291	Troponin I EIA	DE/CA64/00115903
57.	LYME ANTIBODY IGG	K118G	Borelia burgdorferi IgG EIA	DE/CA64/00115904
58.	LYME ANTIBODY IGM	K118M	Borelia burgdorferi IgM EIA	DE/CA64/00115905
59.	EBV ANTIBODIES	K108V K108VM K108N	Epstein-Barr virus VCA IgG EIA Epstein-Barr virus VCA IgM EIA Epstein-Barr virus EBNA IgG EIA	DE/CA64/00115906

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Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.


Represented in the EC by:

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SRN: DE-AR-000006947



Date: **March 07, 2023**


Polmed.de

СЕРТИФІКАТ

про відповідність системи управління якістю

Зареєстрований у Реєстрі

«29» червня 2022 р.

№ UA.SM.214-21

Дійсний до «03» серпня 2024 р.

Перше видання: «04» серпня 2021 р.

ЦИМ СЕРТИФІКАТОМ ВІДПОВІДНОСТІ ПОСВІДЧУЄТЬСЯ,
ЩО СИСТЕМА УПРАВЛІННЯ ЯКОСТІ СТОСОВНО

проектування та розроблення, виробництва та дистрибуції
медичних виробів для діагностики *in vitro*

впроваджена:

ТОВ «ХЕМА»

за адресою: вул. Академіка Єфремова, 23, м. Київ, 03179, Україна

відповідає вимогам ISO 13485:2016;

ДСТУ EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT).

Контроль відповідності сертифікованої системи управління якістю вимогам зазначеного стандарту здійснюється шляхом нагляду, періодичність і процедури якого регламентуються процедурами органу з оцінки відповідності.

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