

FEDERAL SUPERVISORY AGENCY FOR HEALTH CARE AND SOCIAL DEVELOPMENT REGISTRATION CERTIFICATE

#ФСР 2011/10982

May 25, 2011 Valid through: Unlimited

This Certificate was issued to "CHRA" LLC, Russia, 124498, City of Zelenograd, Block 426A, Building 3

to certify that the medical device (medical equipment): <u>Medical hardware and software diagnostic complex</u> for the computation of change in electrophysical human response " CHRA " according to technical specifications 9442-001-62738532-2011

is manufactured by " CHRA "LLC, Russia, 124498, City of Zelenograd, Block 426A, Building 3.

Potential risk class 2a

OKP (All-Russian Classification of Products) 94 4280.

Consistent with the set of registration documents KAP #5896 dated February 22, 2011

by the Order of the Federal Supervisory Agency for Health Care and Social Development dated <u>May 25</u>, <u>2011 #2910-IIp/11</u> was granted permission for production, sale and use in the territory of the Russian Federation.

(Signed) E.A.Telnova, Acting Head of the Federal Supervisory Agency for Health Care and Social Development

013214

(Round seal): *Ministry of Health Care and Social Development *Federal Supervisory Agency for Health Care and Social Development *OGRN 10477 ... 96*

----- Translation Ends -----

Declaration of Translator: Under penalty of perjury under the laws of the United States of America, I, Goncharova Natalya, qualified to translate from both English and Russian; with a Master's Degree in English from the Far Eastern State University, Diploma # 1352; Washington State Court certified, ID #10746, and certified by the State of Washington Department of Social and Health Services, Certificate # 983947 and # TC3329, do hereby certify and declare that this is a true and correct word by word translation done by me to the best of my abilities. This translation consists of one page.

Washington Translation Bureau is a member of NOTIS (local ATA chapter) and WITS.

Washington Translation Bureau P.O. Box 349 Maple Valley, WA 98038 425-432-8797

Natalya Y. Goncharova

State of Washington, County of King Signed before me on May 7, 2013 by Natalya Y.Goncharova

Richard Klein, Public Notary

THE RUSSIAN FEDERATION



CERTIFICATE

OF STATE REGISTRATION OF COMPUTER PROGRAM

#2011610775

CHRA

Copyright holder(s): Limited Liability Company "CHRA"(RU)

Author(s): Mikhailov, Yuriy Ivanovich (RU)

Application #2010617320

Date of application of receipt November 23, 2010

Registered in the Register for Computer Programs on January 13, 2011

(Signed) B.P. Simonov, Head of Federal Service for Intellectual Property, Patents and Trademarks

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"CHRA" Ltd. Zelenograd, Building 426A - 3, 124498 Moscow, Russia



Certificate of Compliance

Electrical safety for

Comprehensive Health Risk Analyser (CHRA)

Date of Issue:

08th August 2011

IMT Reference:

IMT1008181/08/11

Details of Sample:

Model: Hardware-Software Complex CHRA

Date of Receipt:

01st December 2011

Date of Test:

01st December 2011 To 21st December 2011

Test Required:

Test for compliance with: - EN 60950-1:2006

Information technology equipment. Safety. General requirements

Conclusion:

In the configuration tested the sample meets the requirements of the standards

detailed above.

Issue number:

18

This certificate is issued by the Company subject to its General Conditions of Service.

Available upon request and accessible at www.inovamedtechn.com.

Attention is drawn to the limitations of liability, indemnification, jurisdictional, representative restrictions of test samples and sample retention policies defined therein.

This certificate refers only to the sample submitted for test.

This certificate shall not be reproduced except in full without the written approval of IMT LT Ltd.

The **CE** mark shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of Conformity and compliance with all relevant EC Directives.





Authorized Signatory

A.Turchin Operations Manager

IMT Innovative medical technologies "InovaMedTechn" Co. Ltd



DECLARATION OF COMPLIANCE

<u>Limited Liability Company</u> "CHRA" (name of organization, full name of sole proprietor who issued the declaration of compliance)

Registered by Inter-District Office of the the Federal Tax Service #46 in the City of Moscow, 1097746477509 (information on registration of organization, full name of sole proprietor (name of registration authority, date of registration, registration number))

City of Zelenograd, Block 426A, Building 3, 124498 (address, phone, fax number)

represented by General Director Yu.I. Mikhailov (position, full name of the head of organization making the statement)

declares that: <u>Medical hardware and software diagnostic complex for the computation of a change in electrophysical human response</u> "CHRA" (name, type, brand of product declared)

is manufactured according to the Technical Specifications 9442-001-62738532-2011

serial production	(blank)	(information on serial production or
batch (batch number,	details of contract/agreement	t/invoice))

manufactured <u>by Limited Liability Company</u> " CHRA "(name of manufacturer, country, etc)

City of Zelenograd, Block 426A, Building 3, 124498

OK code 005-93 (All-Russian Classification of Products) 94 4280

TN VED of Russia code (blank)

complies with the requirements of <u>National Standard of Russia 50267.0.2-2005</u> (IEC 60601-1-2: 2001), <u>National Standard of Russia 51318.11-2006</u> (CISPR 11-2004), <u>National Standard of Russia 50444-92</u>, <u>National Standard of Russia 50267.0-92</u> (name of regulatory documents to comply with including clauses of these regulatory documents containing the requirements to this type of product)

The Declaration was adopted on the basis of <u>Test protocol #12124-2-10 dated September 20, 2010 of the </u>
<u>Testing Laboratory of the Federal State Unitary Enterprise "Cyclon-test", registration #POCC </u>
<u>RU.0001.21M316, address 141190, Fryazino, Zovodskoi Proezd, 4:</u>

<u>Test protocol #12124-1-10 dated September 20, 2010 of the Testing Laboratory of the Federal State Unitary Enterprise "Cyclon-test", registration #POCC RU.0001.21MO46, address 141190, Fryazino, Zovodskoi Proezd, 4;</u>

<u>Registration Certificate #ΦCP 2011/10982 dated May 25, 2011 of the Federal Supervisory Agency for</u> Health Care and Social Development

Information on documents serving the basis for the adoption of the Declaration

Date of Declaration adoption: March 30, 2012

Declaration of Compliance valid through: March 29, 2012

(Signed) Yu.I. Mikhailov, General Director

Signature, initials, surname

(Round seal): *Limited Liability Company *Moscow *OGRN 1097746477509*" CHRA"

Registration of Declaration of Compliance

Limited Liability Company "Certification authority "CE-cert" (name of certification authority)

Business address: Sokolnicheskaya Sq., Building 4A, Suite 309, City of Moscow, 123001, tel. (499) 270-54-60, e-mail cecercenter@gmail.com OGRN: 1107746515029

Certification #POCC RU.0001.11ИM37 issued on December 30, 2010 by the Federal Technical Regulation and Metrology Agency

Date of registration: March 30, 2012 Declaration registration #POCC RU.UM37. Д00013

(Signed) N.I.Zhidkova initials, surname, of the head of certification authority

(Round seal): *Limited Liability Company "Certification Authority "CE-cert" *LLC CA "CE-cert" *POCC RU.0001.111/M37 *For Certificates*

----- Translation Ends -----

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