

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:

9362-8

Initial Certification Date:

March 28, 2012

Date of Certification Decision:

March 24, 2021

Issuing Date:

March 27, 2021

Valid Until:

March 27, 2024



Intertek



Calin Moldovean

President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada



Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

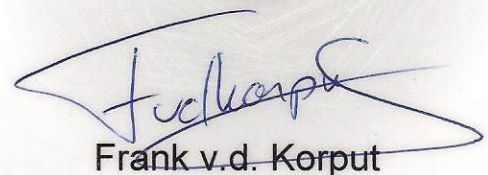
Date of training: April 20th – April 23rd, 2010

System Support Manager:



Jan Oostendorp

System Support Engineer:



Frank v.d. Kerput



SYSTEM OF
INTERNATIONAL
CERTIFICATION

CERTIFICATE

of Quality Management System

SIC.MS.094.ISO13485.1332 dated 11.03.2020 till 10.03.2023

The Certification Center "International Agency Certification" hereby certifies that the Quality Management System of

«Mediclone»

Limited Liability Company

35, Botanicheskaya, Moscow, Russian Federation, 127276

Concerning:

production of medical devices, namely: Reagents and sets of reagents for the determination of human blood groups of ABO Rhesus and Kell systems, as well as antigens and antibodies of the Rhesus system

EN ISO 13485:2016

**"Medical devices. Quality management systems.
Requirements for regulatory purposes"**

Date of Certification:

11.03.2020

Date of Expiry:

10.03.2023

subject to annual approval

2021 r. - till 11.02.2021

2022 r. - till 11.02.2022

Head of certification Body

T. Pogrebnaya



SIC.MS.094.ISO13485.1332

International Certification Agency, 109444, Russian Federation, Moscow, 10 Samarkandsky blvd., Bldg. 1, Apt. 62,
Tel./fax: +8 (903) 223-25-69, Notification letter SIC.02.094,

S.I.C. Global Inc., 346 WIGSTON DR, Suite 4, NORTH BAY, ONTARIO, P1A 1X3, CANADA <http://sic-global.com>

SYSTEM OF INTERNATIONAL CERTIFICATION



SYSTEM OF
INTERNATIONAL
CERTIFICATION

СЕРТИФИКАТ

на систему менеджмента качества
SIC.MS.094.ISO13485.1332 от 11.03.2020 до 10.03.2023
Орган сертификации "Международное Агентство Сертификации"
настоящим сертификатом подтверждает, что система менеджмента
качества

«Медиклон»

Общество с ограниченной ответственностью

127276 Российская Федерация, Москва, ул. Ботаническая, дом 35

Применительно к

производству изделий медицинского назначения, а
именно: «Реагентов и наборов реагентов для
определения групп крови человека систем АВО Резус и
Келл, а также антигенов и антител системы Резус»

соответствует требованиям международного стандарта

EN ISO 13485:2016

**“Изделия медицинские. Системы менеджмента качества.
Системные требования для целей регулирования”**

Дата сертификации:

11.03.2020 г.

Действителен до:

10.03.2023 г.

при условии ежегодного подтверждения
2021 г. - до 11.02.2021
2022 г. - до 11.02.2022

Руководитель органа



Т.Р. Погребная



SIC.MS.094.ISO13485.1332

ОС «Международное Агентство Сертификации», свидетельство Нотификации:

SIC.СВ.643.094 от 21.03.2019 г., 109444, Российская Федерация, г. Москва, б-р Самаркандский, д.10,
корпус 1, кв. 62, Тел./Факс: +7(903) 223-25-69, выданный S.I.C. Global Inc., 346 WIGSTON DR, Suite 4, NORTH BAY, ONTARIO, P1A 1X3, CANADA
<http://sic.com.ua>



ISO 9001 -NF EN ISO 13485



R E A G E N T S

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

TO WHOM TO BE CONCERNED

We, Seppim S.A.S., manufacturers of Elitech Clinical Systems reagents, having our factory at Zone Industrielle, 61500 Sées - France, confirm that our clinical reagents have been validated on Vital Scientific equipment. As such available Elitech Clinical Systems reagent applications for Vital Scientific instruments are CE-IVD compliant.

Reagents, other than Elitech Clinical Systems reagents, are not validated on Vital Scientific equipments, and we also can't know the impact of other reagents on Vital Scientific equipments.

May 22nd, 2012

Noi, subsemnații Seppim S.A.S., compania producătoare a reagenților Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franța, confirmăm, că reagenții au fost testați și validați pe echipamentele Vital Scientific. Pentru acești reagenți există și protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenții cât și echipamentele sunt certificate CE-IVD.

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați și validați la echipamentele Vital Scientific și noi nu cunoaștem compatibilitatea și impactul lor asupra analizatoarelor Vital Scientific.

22 mai 2012

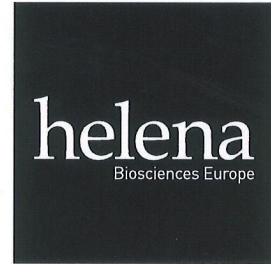
Signed on behalf of the manufacturer
Valérie GOURDON
Regulatory Affairs Manager
COMPANY SEPPIM S.A.S

SEPPIM S.A.S

4 rue Auguste Mattin
Zone Industrielle
61500 SEES – FRANCE
Tél. +33 (0)2 33 81 21 00 - Fax +33 (0)2 33 28 77 51
SIRET : 318 365 228 00036

Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

Training certificate



This is to certify that

Sergiu Sorocovici

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2,V8

Haemostasis products: C-series, AC-4, AggRAM and reagents

Service training: AC-4

Signed:



Sergiu Sorocovici

Date: **31st October - 4th November 2011**

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442

info@helena-biosciences.com
techsupport-hs@helena-biosciences.com

Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

www.helena-biosciences.com

EasyLyte EasyBloodGas EasyStat
Training Certificate

This is to certify that

Sorocovici Sergiu

Of Global Biomarketing Group

*has completed training for the operation and service of the
EasyLyte, EasyBloodGas, and EasyStat analyzers.*

November 25, 2004

Date



MEDICA

Randall Rollins

*Signed: Randall Rollins
Technical Service Manager*