Euroclone
serving science through innovation

DICHIARAZIONE DI CONFORMITA' CE
EC DECLARATION OF CONFORMITY

In accordo a – According to
Allegato III, Direttiva 98/79/CE – *Annex III, Directive 98/79/EC*

Il Fabbricante - *The Manufacturer*:
Euroclone S.p.A.
Via Figino 20/22
20016 Pero (MI) - Italy

dichiara che - *declares that*

i prodotti sotto riportati sono classificati come "Altro tipo di IVD" in conformità ai requisiti descritti nell'Allegato I della Direttiva Europea 98/79/CE, attuata in Italia con il D.Lgs. n 332. Tutti i documenti dei dispositivi diagnostici in vitro riportati nella seguente dichiarazione sono conservati presso gli uffici del fabbricante.

the mentioned products are classified as "All other IVD Medical Device" in accordance with the requirements described in Annex I of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices. All documentation is retained under the premises of the manufacturer.

CODICE - *CODE*	**DESCRIZIONE - *PRODUCT NAME***
EKAMTS008	SYNCHROSET
EKAMTP	CHROMOSOME KIT P
EKAMTM	CHROMOSOME KIT M
EKAMTB100	CHROMOSOME MEDIUM P
EKAMTB500	CHROMOSOME MEDIUM P
EKAMTB100M	CHROMOSOME MEDIUM M
EKAMTB500M	CHROMOSOME MEDIUM M
EKAMTBSY-100.2	CHROMOSOME SYNCHRO MEDIUM P
EKAMTBSY-100.5	CHROMOSOME SYNCHRO MEDIUM P
EKAMTBSY-500	CHROMOSOME SYNCHRO MEDIUM P
EKAMTBSY-100.5M	CHROMOSOME SYNCHRO MEDIUM M

Euroclone S.p.A. - Sede legale: Via Spezia 1 - 20142 Milano (Italy)
Sede amministrativa: Via Figino, 20/22 - 20016 Pero (MI) Italy - Ph. +39 02 38195.1 - Fax +39 02 38195250 - www.euroclone.it - info@euroclone.it
C.F. P.IVA e n°Registro Imprese di Milano 08126390155 – REA Milano 1208538 - Cap. Soc. Euro 3.000.000 i.v.

CODICE - *CODE*	DESCRIZIONE - *PRODUCT NAME*
EKAMTSY-50	CHROMOSOME SYNCHRO KIT P
EKAMTSY-50M	CHROMOSOME SYNCHRO KIT M
EKAMN-240	AMNIODISH
EKAMM100	AMNIOMED® SMART
EKAMG-200	AMNIOMED® PLUS
EKAMS-60F	AMNIOSLIDE SUPERFROST®
EKPHAM01	PHA-M Phytohaemagglutinin M
EK0041B	COLCEMID 10ug/ml in DPBS

Data / *Date*
08-01-2018

Dott. **Franco Aiolfi**
Presidente e Amministratore Delegato
Chief Executive Officer and Managing Director

EUROCLONE S.p.A. - Sede legale: Via Spezia, 1 - 20142 Milano (Italy)
Sede amministrativa: Via Figino, 20/22 - 20016 Pero (MI) Italy - Ph. +39 02 38195.1 - Fax +39 02 38195250 - www.euroclone.it - info@euroclone.it
C.F. P.IVA e n°Registro Imprese di Milano 08126390155 – REA Milano 1208538 - Cap. Soc. Euro 3.000.000 i.v.

Certificate of Registration

In accordance with European Communities Council Directive 98/79/EC as amended, concerning In Vitro Medical Devices as transposed into European national law by the member states.

We hereby declare that:

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled.**
- **Device registrations for the in vitro medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.**

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/KOR/2015/07/01	Issue Date: 30th September 2019	Expiry Date: 31st October 2020

Legal Manufacturer	EU Authorised Representative (EC REP)
SPL Life Sciences Co., Ltd 26 Geumgang-ro 2047 beon-gil, Naechon-Myeon, Pocheon-si, Gyeonggi-do, Korea	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names
Cell Culture Dish
Cell Culture Flask
Cell Culture Plate
Cell Culture Slide
Cell Culture Strainer
Cryovial

Competent Authority	MCCAA Device Registration Reference(s)
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata I-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt	DVC-MT-19-02-000026 DVC-MT-19-02-000027 DVC-MT-19-02-000028 DVC-MT-19-02-000029 DVC-MT-19-02-000030 DVC-MT-19-02-000031

This certificate is issued by:	Authorised Signature:
Advena Limited **Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013.** **Malta. Tel: +44 1926 800153 Email: info@advenamedical.com** **Registered in Malta No. C 76865**	**Anthony Kirby – Managing Director (Malta)**

This certificate is subject to the organisation maintaining their documentation in compliance with the directive stated in this certificate.

This certificate is for the exclusive use of Advena Ltd's client and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Declaration of Conformity

For Cell Culture slide

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Names:	Cell Culture Plate (See Appendix II – Product Listing/Schedule for definitive product list)
Manufacturer:	SPL Life Sciences, Co., Ltd. 26, Geumgang-ro 2047 beon-gil, Naechon-myeon, Pocheon-si, Gyeonggi-do , Korea
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	In vitro human cell culture and sample storage for assisting diagnosis
Intended User:	Professional use
IVD Directive Category:	General (neither listed in Annex II, nor intended for self testing)
Notified Body:	Not applicable
IVD Directive Assessment route:	Annex III of Directive 98/79/EC
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Choi Ik Hwang **Position** Quality Representative

Signed  **Date** 09/01/2019

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
30101	TC non-treated 1 well glass culture slide, clear	
30111	TC non-treated 1 well glass culture slide, black	
30121	TC non-treated 1 well glass culture slide, white	
30401	TC treated 1 well dlux culture slide, clear	
30501	TC treated 1 well flux culture slide, clear	
30102	TC non-treated 2 well glass culture slide, clear	
30112	TC non-treated 2 well glass culture slide, black	
30122	TC non-treated 2 well glass culture slide, white	
30402	TC treated 2 well dlux culture slide, clear	
30502	TC treated 2 well flux culture slide, clear	
30104	TC non-treated 4 well glass culture slide, clear	
30114	TC non-treated 4 well glass culture slide, black	
30124	TC non-treated 4 well glass culture slide, white	
30404	TC treated 4 well dlux culture slide, clear	
30504	TC treated 4 well flux culture slide, clear	
30108	TC non-treated 8 well glass culture slide, clear	
30118	TC non-treated 8 well glass culture slide, black	
30128	TC non-treated 8 well glass culture slide, white	
30408	TC treated 8 wel8 dlux culture slide, clear	
30508	TC treated 8 well flux culture slide, clear	
33101	TC non-treated glass culture hybridwell, clear	
33201	TC treated dlux culture hybridwell, clear	
33301	TC treated flux culture hybridwell, clear	

Version History

Version	Compiled by	Date	Description
1.0	Ik Hwang Choi	09/01/2019	First issue

LNE
Le progrès, une passion à partager

Certification Médical-Santé G MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 10229 rev. 9

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

PRINCE MEDICAL
ZA La Sente du Moulin
60530 ERCUIS FRANCE

pour les activités
for the activities

Conception, fabrication et commercialisation de dispositifs médicaux stériles et non stériles pour différents domaines (Voir addendum). Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène de dispositifs médicaux selon l'ISO 11135-1 : 2007. Fabrication en sous-traitance de lignes externes, dans le domaine de la radiologie.

Design, manufacturing and sales of sterile and non sterile medical devices for various fields (See addendum). Validation and routine control of sterilization by ethylene oxide of medical devices according to ISO 11135-1 : 2007. Manufacturing in subcontracting of external lines in the field of the radiology.

réalisées sur le(s) site(s) de
performed on the location(s) of

PRINCE MEDICAL
Z.A. La Sente du Moulin 60530 ERCUIS FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **June 14th, 2018 (included)**
Valable jusqu'au */ Expiry date :* **December 30th, 2020 (included)**
Etabli le */ Issued on :* **June 14th, 2018**

Laboratoire national de métrologie et d'essais LNE

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0038
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ_SPE-V0-04-2016

LNE N° 10229–9
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification

Modifie le certificat 10229-8

LNE
Le progrès, une passion à partager

Certification Médical-Santé G MED

Addendum au certificat n° 10229 rev. 9 page 1/1
Addendum of the certificate n° 10229 rev. 9
Dossier / *File* N° P159766

Ce certificat couvre les activités et le site suivant / *This certificate covers the following activities and site:*

PRINCE MEDICAL - Z.A. La Sente du Moulin - 60530 ERCUIS - FRANCE

Version française :

- **Conception, fabrication et commercialisation de dispositifs médicaux stériles et non stériles dans les domaines de l'urologie, de la gastro-entérologie, de la pneumologie, de la gynécologie et de l'endoscopie.**
- **Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène de dispositifs médicaux selon l'EN ISO 11135-1.**
- **Fabrication en sous-traitance de lignes externes, dans le domaine de la radiologie.**

Version anglaise :

- *Design, manufacturing and sales of sterile and non sterile medical devices in the fields of urology, gastro-enterology, pneumology, gynecology and endoscopy.*
- *Validation and routine control of sterilization by ethylene oxide of medical devices according to EN ISO 11135-1.*
- *Manufacturing in subcontracting of external lines in the field of radiology.*

****

1 site / *1 site*

Laboratoire national de métrologie et d'essais • LNE

On behalf of the G-MED Certification Director
Béatrice LYS
G-MED Certification Technical Director

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié par l'autorité compétente française en matière de dispositifs médicaux n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

THE STANDARDS INSTITUTION OF ISRAEL AS AN IQNET PARTNER

Hereby certify that the organization

Biological Industries Israel Beit Haemek Ltd.

Postal Service Oshrat, Beit Ha'emek, Israel

For the following scope:

Design, development, manufacturing, marketing and sale of animal and human culture products whithin biological and clinical research. Manufacturing and scaling-up custom media and contract manufacturing media.

Has implemented and maintains a Quality Management System
which fulfils the requirement of the following standard:

ISO 9001:2015

Issued on:	28/11/2018
Date of expiration:	27/11/2021
Date of initial approval:	01/02/1995

Registration number: IL - 86069

Alex Stoichitoiu
President of IQNet

Ilan Carmit
Acting Director General

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland*
Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia*
SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.sii.org.il

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

THE STANDARDS INSTITUTION OF ISRAEL AS AN IQNET PARTNER

Hereby certify that the organization

Biological Industries Israel Beit Haemek Ltd.

Postal Service Oshrat, Beit Ha'emek, Israel

For the following scope:

1. Design, manufacture and distribution of: a.Research products for cell culture, cell biology and molecular biology. b. Medical devices including in-vitro diagnostic products. c.Cell culture reagents for industrial bio- processing. 2. Contract manufacturing of research products and aseptic sterile medical devices including in vitro diagnostic products.

Has implemented and maintains a Quality Management System which fulfils the requirement of the following standard:

ISO 13485:2016

Issued on:	28/11/2018
Date of expiration:	27/11/2021
Date of initial approval:	10/04/2006

Registration number: IL - 97375

Alex Stoichitoiu
President of IQNet

Ilan Carmit
Acting Director General

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland*
Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia*
SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.sii.org.il

DECLARATION OF CONFORMITY

Application of Council Directive: 98/79/EC

Manufacturers name:	Biological Industries Israel Beit Haemek Ltd.
Manufacturers address:	Kibbutz Beit Haemek 2511500 Israel
Generic Product Group:	Chromosome culture kits-Reagents
EDMS Code:	13-07-01-01-00

I, the undersigned, hereby declare on our own responsibility that the product(s) specified above meet(s) all the provisions of the Directive 98/79/EC as per ANNEX III section 2-5 of the European Parliament and of the Council, on In Vitro diagnostic medical devices. These products are classified as "Other device not listed under Annex II and self-testing" according to the Directive 98/79/EC.

BIOLOGICAL INDUSTRIES ISRAEL BEIT HAEMEK LTD.

Ravid Grimberg	VP of QA&RA	11/11/2018
Signature	Position	Date

Authorized Representative in the EU:

MedNet GmbH
Borkstraβe 10, 48163 Münster, Germany
Tel: 49-2513-2266-0
Fax: 49-2513-2266-22

Catalogue Number	Product Name
01-190-1	BIO-AMF™ 1 Basal Medium
01-192-1	BIO-AMF™ 1 Supplement
01-194-1	BIO-AMF™ 2
01-196-1	BIO-AMF™ 3
01-198-1	BIO-PB™ Karyotyping Medium without PHA
01-199-1	BIO-MARROW™ Karyotyping Medium without conditioned medium
01-200-1	BIO-HEMATO™ Karyotyping Medium with conditioned medium
01-201-1	BIO-PB™ Karyotyping Medium with phytohemagglutinin
01-934-1	Sodium Citrate Solution (0.8%)
12-003-1	Colchicine
12-004-1	Colcemid
12-005-1	Potassium Chloride Solution 0.075M
12-006-1	Phytohaemagglutinin M (PHA-M) for the stimulation of peripheral blood lymphocytes
12-008-60	Cell Synchronization Kit
12-009-1	PHA (M) liquid

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60124131 0001

Report No.: 15094396 004

Manufacturer:
Shanghai Mekon Medical
Devices Co., Ltd.
526, No. 697-3 Lingshi Road
200072 Shanghai
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60109368 0001

Expiry Date: 2021-07-06

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-10-16

Date: 2017-10-16

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60124131 0001
Report No.: 15094396 004

Manufacturer:
Shanghai Mekon Medical Devices Co., Ltd.
526, No. 697-3 Lingshi Road
200072 Shanghai
China

Products:

Infusion Sets, Disposable Needles, Scalp Vein Sets, Dental Needles for Single Use, Blood-Collecting Needles, Disposable Insulin Pen Needles, Syringes, Transfusion Sets, Burette-Type Infusion Sets, Fistula Needles, Syringes for Insulin, Sterile I.V. Catheter for Single Use, Huber Needles, Biopsy Needles, Safety Needles, Self-destruction Safety Syringes, Safety Scalp Vein Sets, Safety Blood-collecting Needles, Safety Insulin Needles for Single Use, Extension Sets, Sterile Irrigation Needles for Single Use;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Infusion Connector and Accessory for Single Use, Stopcocks for Single Use, Urinal Bags, Blunt Filter Needles for Single Use

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2017-10-16

X. Ren