

CERTIFICATE

This is to certify that the Quality Management System of
Biological Industries Israel Beit Haemek
Ltd.

Postal Service Oshrat , Beit Ha'emek , Israel

Has been assessed and complies with the requirements of :
ISO 9001:2015

This Certificate is Applicable to

**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.**

Initial Approval:
Certification Decision:
Valid Until:

01/02/1995
30/11/2021
30/11/2024

Certificate No.: 86069

SII-QCD assumes no liability to any party other than the client, and then only in accordance with the agreed upon Certification Agreement.
This certificate's validity is subject to the organization maintaining their system in accordance with SII-QCD requirements for system certification. The
continued validity may be verified via scanning the code with a smartphone, or via website www.sii.org.il. This certificate remains the property of SII-QCD.


Dr. Gilad Golub
CEO




Avital Weinberg
Director, Quality & Certification Division





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

THE STANDARDS INSTITUTION OF ISRAEL

has issued an IQNet recognized certificate that the organization:

**Biological Industries Israel Beit Haemek
Ltd.**

Postal Service Oshrat, Beit Ha'emek, Israel

Has implemented and maintains a Quality Management System

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.

which fulfils the requirement of the following standard:

ISO 9001:2015

Issued on:	30/11/2021
Date of initial approval:	01/02/1995
Date of expiration:	30/11/2024

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

Registration number: IL - 86069




Alex Stoichitoiu
President of IQNet


Avital Weinberg
Director, Quality & Certification Division 

IQNet Partners*:

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
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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

CERTIFICATE

This is to certify that the Quality Management System of
Biological Industries Israel Beit Haemek
Ltd.

Postal Service Oshrat , Beit Ha'emek , Israel

Has been assessed and complies with the requirements of :
ISO 13485:2016

This Certificate is Applicable to

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.

Initial Approval:
Certification Decision:
Valid Until:

10/04/2006
30/11/2021
30/11/2024

Certificate No.: 97375

SII-QCD assumes no liability to any party other than the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with SII-QCD requirements for system certification. The continued validity may be verified via scanning the code with a smartphone, or via website www.sii.org.il. This certificate remains the property of SII-QCD.


Dr. Gilad Golub
CEO




Avital Weinberg
Director, Quality & Certification Division



THE STANDARDS INSTITUTION OF ISRAEL




The standards Institution of Israel
42 Chaim Levanon St,
Tel-Aviv 6997701



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

THE STANDARDS INSTITUTION OF ISRAEL

has issued an IQNet recognized certificate that the organization:

**Biological Industries Israel Beit Haemek
Ltd.**

Postal Service Oshrat, Beit Ha'emek, Israel

Has implemented and maintains a Quality Management System

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.

which fulfils the requirement of the following standard:

ISO 13485:2016

Issued on:	30/11/2021
Date of initial approval:	10/04/2006
Date of expiration:	30/11/2024

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

Registration number: IL - 97375




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President of IQNet


Avital Weinberg
Director, Quality & Certification Division 

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FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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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: Media For Tissue Culture

EDMS Code: 14-04-01-02-00

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



Heller Japheth, Romina
Signature

Regulatory Affairs
Specialist
Position

26/11/2020
Date

Authorized Representative in the EU:

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





Catalogue Number	Product Name
01-010-1	BGJ Medium
01-015-1	Basal Medium Eagle – Earle's Salts Base
01-015-5	Basal Medium Eagle X10 – Earle's Salts Base
01-020-1	BME – Hank's Salts
01-025-1	MEM Eagle – Earle's Salts Base
01-025-5	MEM Eagle X10 – Earle's Salts Base
01-025-9	MEM Eagle X2 – Earle's Salts Base
01-035-1	MEM Eagle – Hank's Salts Base
01-040-1	MEM Eagle – Earle's Salts Base with Non-Essential Amino Acids
01-042-1	MEM – Alpha with 1.0g/l D-Glucose (Low Glucose)
01-043-1	MEM – Alpha with 4.5g/l D-Glucose (High Glucose)
01-045-1	MEM Eagle for Suspension Culture– Earle's Salts Base
01-050-1	DMEM with 1.0g/l D-Glucose (Low Glucose)
01-050-5	DMEM X10 with 1.0g/l D-Glucose (Low Glucose)
01-052-1	DMEM with 4.5g/l D-Glucose (High Glucose) and 4mM L-Glutamine
01-053-1	DMEM with 4.5g/l D-Glucose (High Glucose), without Phenol Red
01-054-1	DMEM with 4.5g/l D-Glucose (High Glucose), without L-Methionine
01-055-1	DMEM with 4.5g/l D-Glucose (High Glucose)
01-055-4	DMEM X5 with 4.5g/l D-Glucose (High Glucose)
01-055-5	DMEM X10 with 4.5g/l D-Glucose (High Glucose)
01-055-9	DMEM X2 with 4.5g/l D-Glucose (High Glucose)
01-056-1	DMEM with 4.5g/l D-Glucose (High Glucose) and L-Alanyl-L-Glutamine (Stable Glutamine)
01-057-1	DMEM without D-Glucose, L-Glutamine and Sodium Pyruvate
01-058-1	Iscove's Modified Dulbecco Medium
01-059-1	Modified MCDB-153
01-060-1	Glasgow MEM
01-075-1	McCoy's 5A Medium (Modified)
01-080-1	M-199 – Earle's Salts Base
01-080-5	M-199 X10 – Earle's Salts Base
01-085-1	M-199 – Hank's Salts Base
01-090-1	F-10 (HAM) Nutrient Mixture
01-090-5	F-10 (HAM) Nutrient Mixture X10
01-095-1	F-12 (HAM) Nutrient Mixture
01-095-5	F-12 (HAM) Nutrient Mixture X10
01-100-1	RPMI 1640
01-101-1	RPMI 1640 without L-Glutamine and D-Glucose
01-103-1	RPMI 1640 without L-Glutamine and Phenol Red
01-104-1	RPMI 1640 without L-Glutamine
01-104-5	RPMI 1640 10X without L-Glutamine
01-106-1	RPMI 1640 with Hepes
01-107-1	RPMI Dutch modification
01-110-1	Waymouth's MB 752/1 Medium
01-115-1	Leibovitz L-15 Medium
01-145-1	Fischer's Medium



Catalogue Number	Product Name
01-150-1	Schneider's Drosophila Medium
01-155-1	Grace's Insect Medium
01-170-1	DMEM: F-12 (HAM) 1:1
01-171-1	Mouse ES Basal medium
01-821-1	CMRL-1066
01-830-1	MCDB-105
01-925-1	Modified F-10 (HAM) without antibiotics
01-926-1	Modified F-10 (HAM) with antibiotics
01-996-1	ACL-4 Medium RPMI Based with L-Glutamine
05-010-1	DCCM-1
05-015-1	DCCM-2
05-040-1	LPM
05-050-1	BIO-INSECT-1
05-060-1	BIO-MPM-1
05-061-1	BIO-CHO-1
05-062-1	BIO-CHO-2
05-066-1	NutriVero VP1
05-067-1	NutriVero VP2
05-068-1	Nutrivero Flex 10
05-080-1	BIOTARGET
05-100-1	NutriStem® hPSC XF
05-102-1	AF NutriStem® hPSC XF
05-200-1	MSC Nutristem® XF Basal Medium
05-201-1	MSC Nutristem® XF Supplement Mix
05-202-1	MSC Nutristem® XF PRF Basal Medium
05-600-1	BIOGRO-1
05-610-1	BIOGRO-2
05-620-1	BIOGRO-CHO Supplement
06-5100-01	NutriStem® hPSC XF without TGF & FGF
CFV3FA4	4Cell Nutrivero Flex 10
CFV3FA4 PRF	4Cell Nutrivero Flex 10 without Phenol Red

Action Name	User Name	Title	Signature Date
Submit	Romina Heller Japheth	Regulatory Affairs Professional	26-Nov-2020 13:58 (GMT+2)