

# 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 within 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](http://www.sii.org.il). This certificate remains the property of SII-QCD.



R.N 511513145

  
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:

**Design, development, manufacturing, marketing and sale of animal and human culture products within 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\*:**

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 EAGLE Certification Group USA  
 FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
 IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
 NYCE-SIGE Mexico 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

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

[www.sii.org.il](http://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](http://www.sii.org.il). This certificate remains the property of SII-QCD.

  
Dr. Gilad Golub  
CEO



  
Avital Weinberg  
Director, Quality & Certification Division



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Tel-Aviv 6997701



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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**Biological Industries Israel Beit Haemek  
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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
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 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

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