

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
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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)