

## Life Technologies

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**EC DECLARATION OF CONFORMITY**  
**Directive 98/79/EC**  
**Annex III**

**Life Technologies Ltd**  
3 Fountain Drive  
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Paisley PA4 9RF  
Scotland

Life Technologies Limited declares that the *In Vitro Diagnostic* products listed on the following pages are in conformity with all applicable provisions of Council Directive 98/79/EC of 27 October 1998 on *In Vitro Diagnostic Medical Devices* and are entitled to bear the CE Mark.

**Conformity Assessment Route:** *In Vitro Diagnostic Medical Device*, conformity assessment procedure, article 9, Annex III.

**Classification:** Non Annex II, Non Self-Test Devices

**Standards Applied:** EN ISO 13485:2016, BS EN ISO 14971:2012

**Product Description:** Cell Culture Products

**Nomenclature:** GIVD 14.04.01.02 Media for Tissue Culture  
14.04.01.04 Other Tissue Culture Additives and Solutions  
GMDN 58567

Life Technologies confirms that the products listed below are manufactured under a controlled Quality Management System and maintains a post market surveillance and vigilance procedure.

Signed:

Date: 14 Sept 2020



Ross Kerr  
Regulatory Affairs Specialist, Regulatory Affairs  
On behalf of Life Technologies Ltd

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DMR0000789  
Revision 14

**Life Technologies**

GIVD 14.04.01.02 Media for Tissue Culture			
Item Number	Product Description	Media Format	Pack Size
<b>BME, Basal Media (Eagle)</b>			
41010026	BME, Basal Medium (Eagle) (1X) with Earle's Salts, without L-Glutamine	Liquid	500ml
41010109			10 x 500ml
<b>Dulbecco's MEM</b>			
11880028	Dulbecco's Modified Eagle Medium without Phenol Red, without L-Glutamine	Liquid	500ml
11880036			10 x 500ml
<b>Dulbecco's MEM (High Glucose)</b>			
10938025	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) without L-Glutamine	Liquid	500ml
10938026			10 x 500ml
11960044	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, without glutamine	Liquid	500ml
11960085			10 x 500ml
11965084	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, with glutamine	Liquid	1000ml
11965126			6 x 1000ml
11995040	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, with glutamine, with Sodium Pyruvate	Liquid	1000ml
11995081			6 x 1000ml
11995065	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, with glutamine, with Sodium Pyruvate	Liquid	500ml
11995073			10 x 500ml
11995123	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, with L-glutamine, without Sodium Pyruvate	Liquid	10L
11965092	Dulbecco's Modified Eagle Medium (D-MEM), high glucose, with glutamine, without Sodium Pyruvate	Liquid	500ml
11965118			10 x 500ml
21063029	Dulbeccos Modified Eagle Medium (High Glucose) with L-Glutamine, 4500 mg/L D-Glucose, 25mM HEPES, without Sodium Pyruvate	Liquid	500ml
21063045			10 x 500ml
21969035	Dulbeccos Modified Eagle Medium (High Glucose) without L-Glutamine, with Sodium Pyruvate	Liquid	500ml
21969036			10 x 500ml
31966021	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) with GlutaMAX™ I, 4500 mg/L D-Glucose, Sodium Pyruvate	Liquid	500ml
31966047			10 x 500ml
32430027	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) with GlutaMAX™ I, 4500 mg/L D-Glucose, 25 mM HEPES, without Sodium Pyruvate	Liquid	500ml
32430100			10 x 500ml
41965039	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) with L-Glutamine, 4500 mg/L D-Glucose, without Sodium Pyruvate	Liquid	500ml
41965062			10 x 500ml
41965047			1000ml
41965120			6 x 1000ml
41966029	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High	Liquid	500ml

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41966052	Glucose) with L-Glutamine, 4500 mg/L D-Glucose, Sodium Pyruvate		10 x 500ml
41966161			10L
42430025	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) with L-Glutamine, 4500 mg/L D-Glucose, 25 mM HEPES, without Sodium Pyruvate	Liquid	500ml
42430082			10 x 500ml
61965026	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (High Glucose) with GlutaMAX™ I, 4500 mg/L D-Glucose, without Sodium Pyruvate	Liquid	500ml
61965059			10 x 500ml
61965240			5L
<b>Dulbecco's MEM (Low Glucose)</b>			
21885025	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (Low Glucose) with GlutaMAX™ I, 1000 mg/L D-Glucose, Sodium Pyruvate	Liquid	500ml
21885108			10 x 500ml
22320022	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (Low Glucose) with L-Glutamine, 1000 mg/L D-Glucose, Sodium Pyruvate, 25 mM HEPES	Liquid	500ml
22320030			10 x 500ml
31885023	Dulbecco's Modified Eagle Medium (D-MEM) (1X), (Low Glucose) with L-Glutamine, 1000 mg/L D-Glucose, Sodium Pyruvate	Liquid	500ml
31885049			10 x 500ml
<b>Dulbecco's MEM: F-12 Nutrient Mixture</b>			
10565018	D-MEM/F-12 (1:1) (1X) with GlutaMAX™ I	Liquid	500ml
10565042			10 x 500ml
11330032	DMEM/F-12 (1:1) Dulbeccos Modified Eagle Medium F-12 Nutrient Mixture (Ham)	Liquid	500ml
11330057			10 x 500ml
11320074	D-MEM/F-12 (1:1) (1X), with L-Glutamine, without HEPES	Liquid	500ml
11320084			10 x 500ml
21331020	D-MEM/F-12 (1:1) (1X) without L-Glutamine	Liquid	500ml
21331046			10 x 500ml
31330038	D-MEM/F-12 (1:1) (1X) with L-Glutamine, 15 mM HEPES	Liquid	500ml
31330095			10 x 500ml
31331028	D-MEM/F-12 (1:1) (1X) with GlutaMAX™ I	Liquid	500ml
31331093			10 X 500ml
<b>Leibovitz's L-15 Medium</b>			
11415049	Leibovitz's L-15 Medium (1X), with L-Glutamine	Liquid	500ml
11415056			10 x 500ml
31415029	Leibovitz's L-15 Medium (1X), with GlutaMAX™ I	Liquid	500ml
31415086			10 x 500ml
<b>Medium 199 with Earle's Salts</b>			
21157029	Medium 199 (2X), without Phenol Red	Liquid	250ml
21157030			10 x 250ml
21180021	Medium 199 (10X)	Liquid	500ml
21180022			10 x 500ml
31150022	Medium 199 (1X), with Earle's Salts, L-Glutamine	Liquid	500ml

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31150030			10 x 500ml
31153026	Medium 199 (1X), with Earle's Modified Salts	Liquid	500ml
31153027			10 x 500ml
41150020	Medium 199 (1X), with Earle's Salts, GlutaMAX™-I	Liquid	500ml
41150087			10 x 500ml
<b>Medium 199 with Hanks' Salts</b>			
22350029	Medium 199 (1X), with Hanks' Salts, L-Glutamine, 25 mM HEPES	Liquid	500ml
22350078			10 x 500ml
<b>Minimum Essential Medium MEM with Earle's Salts with L-Glutamine</b>			
31095029	Minimum Essential Medium (MEM) (1X), with Earle's Salts, L-Glutamine	Liquid	500ml
31095052			10 x 500ml
41090028	Minimum Essential Medium (MEM) (1X), with Earle's Salts, GlutaMAX™ I	Liquid	500ml
41090093			10 x 500ml
42360024	Minimum Essential Medium (MEM) (1X), with Earle's Salts, GlutaMAX™ I, 25 mM HEPES	Liquid	500ml
42360081			10 x 500ml
<b>Minimum Essential Medium (MEM) with Earle's Salts. without L-Glutamine</b>			
10370047	Minimum Essential Medium (MEM) (1X), with Earle's Salts, Non Essential Amino Acids, without L-Glutamine	Liquid	500ml
10370070			10 x 500ml
51200046	Minimum Essential Medium (MEM) (1X), with Earle's Salts, without L-Glutamine, Phenol Red	Liquid	500ml
51200087			10 x 500ml
21090022	Minimum Essential Medium (MEM) (1X), with Earle's Salts, without L-Glutamine	Liquid	500ml
21090055			10 x 500ml
21430020	Minimum Essential Medium (MEM) (10X), with Earle's Salts, without L-Glutamine, Sodium Bicarbonate	Liquid	500ml
21430079			10 x 500ml
32360026	Minimum Essential Medium (MEM) (1X), with Earle's Salts, 25 mM HEPES, without L-Glutamine	Liquid	500ml
32360034			10 x 500ml
<b>Minimum Essential Medium (MEM) with Hanks' Salts. with L-Glutamine</b>			
21575022	Minimum Essential Medium (MEM) (1X), with Hanks' Salts, L-Glutamine	Liquid	500ml
21575097			10 x 500ml
<b>Modified Eagle Medium</b>			
21935028	Modified Eagle Medium (2X), with L-Glutamine, without Phenol Red	Liquid	250ml
21935029			10 x 250ml
<b>RPMI 1640 Medium</b>			
11835063	RPMI 1640 Medium (1X), with L-Glutamine, without Phenol Red	Liquid	500ml
11835105			10 x 500ml
11875085	RPMI Medium 1640 (1X), with L-Glutamine	Liquid	1000ml
11875135			6 x 1000ml
11875093			500ml
11875119			10 x 500ml
21875034			500ml
21875091	RPMI 1640 Medium (1X), with L-Glutamine	Liquid	10 x 500ml
21875042			100ml

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21875109			20 x 100ml
21875059			1000ml
21875158			6 x 1000ml
31870017			100ml
31870082	RPMI 1640 Medium (1X), without L-Glutamine	Liquid	20 x 100ml
31870025			500ml
31870074			10 x 500ml
32404014	RPMI 1640 Medium (1X), without Phenol Red	Liquid	500ml
32404015			10 x 500ml
42401018	RPMI 1640 Medium (1X), with 20MM HEPES without L-Glutamine	Liquid	500ml
42401042			10 x 500ml
42402016	RPMI 1640 Medium (1X), with 25MM HEPES without L-Glutamine	Liquid	500ml
42402017			10 x 500ml
52400017	RPMI 1640 Medium (1X), with L-Glutamine, 25 mM HEPES	Liquid	100ml
52400058			20 x 100ml
52400025			500ml
52400041			10 x 500ml
61870010	RPMI 1640 Medium (1X), with GlutaMAX™ I	Liquid	500ml
61870044			10 x 500ml
72400013	RPMI 1640 Medium (1X), with GlutaMAX™ I, 25 mM HEPES	Liquid	100ml
72400112			20 x 100ml
72400021			500ml
72400054			10 x 500ml

AmnioMax Complete Medium II			
11269016	AmnioMAX II Complete Medium (1X)	Liquid	100ml
11269097			20 x 100ml
AmnioMax Basal Medium			
17001074	AmnioMAX C-100 Basal Medium (1X)	Liquid	450ml
17001094			10 x 450ml

Balanced Salt Solutions			
GIVD 14.04.01.04 Other Tissue Culture Additives and Solutions			
Dulbecco's Phosphate Buffered Saline, D-PBS			
14040083	Dulbecco's Phosphate Buffered Saline (D-PBS) (1X), with Calcium, Magnesium, without Phenol Red	Liquid	100ml
14040166			20 x 100ml
14040091			500ml
14040174			10 x 500ml
14040117			1000ml
14040224			6 x 1000ml
14080048	Dulbecco's Phosphate Buffered Saline (D-PBS) (10X), with Calcium, Magnesium	Liquid	500ml
14080089			10 x 500ml
14190086	Dulbecco's Phosphate Buffered Saline (D-PBS) (1X), without	Liquid	100ml

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14190185	Calcium, Magnesium, Phenol Red		20 x 100ml		
14190094			500ml		
14190169			10 x 500ml		
14190136			1000ml		
14190326			6 x 1000ml		
14190144			500ml		
14190250			10 x 500ml		
14190230			5L		
14190240			10L		
14190342			5L		
14190367			20L		
14200059			Dulbecco's Phosphate Buffered Saline (D-PBS) (10X), without Calcium, Magnesium	Liquid	100ml
14200091					20 x 100ml
14200067					500ml
14200083	10 x 500ml				
<b>Earle's Balanced Salt Solution (EBSS)</b>					
14155048	Earle's Balanced Salt Solution (EBSS) (1X), without Calcium, Magnesium, Phenol Red	Liquid	500ml		
14155046			10 x 500ml		
<b>Hank's Balanced Salt Solution (HBSS)</b>					
14025050	Hanks' Balanced Salt Solution (HBSS) (1X), with Calcium, Magnesium, without Phenol Red	Liquid	500ml		
14025100			10 x 500ml		
14025076			1L		
14060040	Hanks' Balanced Salt Solution (HBSS) (10X), without Sodium Bicarbonate	Liquid	500ml		
14060073			10 x 500ml		
14065049	Hanks' Balanced Salt Solution (HBSS) (10X), without Phenol Red, Sodium Bicarbonate	Liquid	500ml		
14065072			10 x 500ml		
14170070	Hanks' Balanced Salt Solution (HBSS) (1X), without Calcium, Magnesium	Liquid	100ml		
14170146			20 x 100ml		
14170088			500ml		
14170138			10 x 500ml		
14175046	Hanks' Balanced Salt Solution (HBSS) (1X), without Calcium, Magnesium, Phenol Red	Liquid	100ml		
14175137			20 x 100ml		
14175053			500ml		
14175129			10 x 500ml		
14180046	Hanks' Balanced Salt Solution (HBSS) (10X), without Calcium, Magnesium, Sodium Bicarbonate	Liquid	500ml		
14180080			10 x 500ml		
14185045	Hanks' Balanced Salt Solution (HBSS) (10X), without Calcium, Magnesium, Phenol Red, Sodium Bicarbonate	Liquid	500ml		
14185087		Liquid	10 x 500ml		
24020083	Hanks' Balanced Salt Solution (HBSS) (1X), with Calcium, Magnesium, Phenol Red	Liquid	100ml		
24020141			20 x 100ml		
24020091			500ml		
24020133			10 x 500ml		

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Phosphate-Buffered Saline (PBS)			
10010015	Phosphate-Buffered Saline (PBS) (1X), pH: 7.4 ± 0.05	Liquid	500ml
10010056			10 x 500ml
10010023			500ml
10010049			10 x 500ml
20012019	Phosphate-Buffered Saline (PBS) (1X), pH: 7.2 ± 0.05	Liquid	500ml
20012068			10 x 500ml
70011036	Phosphate-Buffered Saline (PBS) (10X), pH: 7.4 ± 0.05	Liquid	500ml
70011051			10 x 500ml
70013016			500ml
70013065	Phosphate-Buffered Saline (PBS) (10X), pH: 7.2 ± 0.05	Liquid	10 x 500ml
Cell Culture Reagents			
GIVD 14.04.01.04 Other Tissue Culture Additives and Solutions			
15630049	HEPES Buffer Solution 1 M	Liquid	20ml
15630056			100ml
15630122			20 x 100ml
22561021	Minimum Essential Medium (MEM) α Medium (1X), with Earles Salts, L-Glutamine without Ribonucleosides, Deoxyribonucleosides	Liquid	500ml
22561054			10 x 500ml
22571020	Minimum Essential Medium (MEM) α Medium (1X), with Earles Salts, L-Glutamine, Ribonucleosides, Deoxyribonucleosides	Liquid	500ml
22571038			10 x 500ml
32561029	Minimum Essential Medium (MEM) α Medium (1X), with Earles Salts, GlutaMAX™I, without Ribonucleosides, Deoxyribonucleosides	Liquid	500ml
32561094			10 x 500ml
32571028	Minimum Essential Medium (MEM) α Medium (1X), with Earles Salts, GlutaMAX™I, Ribonucleosides, Deoxyribonucleosides	Liquid	500ml
32571093			10 x 500ml
11130036	MEM Amino Acids Solution (50X), without L-Glutamine	Liquid	100ml
11130077			20 x 100ml
11140035	MEM Non Essential Amino Acids (100X), without L-Glutamine	Liquid	100ml
11140068			20 x 100ml
11120001	MEM Vitamins Solution (100X)	Liquid	1000ml
11120061			6 x 1000ml
11120037			100ml
11120062			20 x 100ml