

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
Bio SB Antibodies for Immunohistochemistry, amended (2017 new antibodies)	See Appendix A. List of Products 2017 New Antibodies Attached hereto and made part of this Declaration

MANUFACTURER		
Name of Company	Address	Representative
Bio SB, Inc.	69 Santa Felicia Drive Santa Barbara CA 93117 USA	Marianne Henry Quality Assurance Representative

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
General IVD, Self-Certify	Annex III of IVDD 98/79/EC Council Directive	EN ISO 14971:2012 EN ISO 13485: 2003

Bio SB, Inc., declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

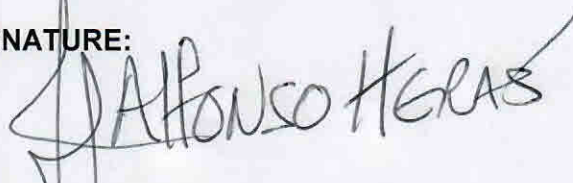
COMPANY REPRESENTATIVE

TITLE: President

DATE:

30/03/2017

SIGNATURE:



Dr. Alfonso Heras
Bio SB Inc.

Appendix A: List of Products, Bio SB

2017 New Antibodies

Catalog #	Product Description	Host	Clone	Isotype	Package Insert
BSB 3286	Tinto Alpha Synuclein MMab, 3 ml, predilute	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3287	Tinto Alpha Synuclein MMab, 7 ml, predilute	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3288	Tinto Alpha Synuclein MMab, 15 ml, predilute	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3289	Alpha Synuclein MMab, 0.1 ml, concentrate	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3290	Alpha Synuclein MMab, 0.5 ml, concentrate	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3291	Alpha Synuclein MMab, 1 ml, concentrate	MMab	BSB-114	IgG2a/K	PI 3291
BSB 3292	Alpha Synuclein MMab, 5 + control slides				
BSB 3441	Tinto Amyloid Beta RMab, 3mL, Predilute	RMab	RBT-A4	IgG	PI 3446
BSB 3442	Tinto Amyloid Beta RMab, 7mL, Predilute	RMab	RBT-A4	IgG	PI 3446
BSB 3443	Tinto Amyloid Beta RMab, 15mL, Predilute	RMab	RBT-A4	IgG	PI 3446
BSB 3444	Amyloid Beta RMab, 0.1mL, Concentrate	RMab	RBT-A4	IgG	PI 3446
BSB 3445	Amyloid Beta RMab, 0.5mL, Concentrate	RMab	RBT-A4	IgG	PI 3446
BSB 3446	Amyloid Beta RMab, 1mL, Concentrate	RMab	RBT-A4	IgG	PI 3446
BSB 3447	Amyloid Beta RMab, 5 + control Slides				
BSB 3293	Tinto ATRX MMab, 3mL, Predilute	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3294	Tinto ATRX MMab, 7mL, Predilute	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3295	Tinto ATRX MMab, 15mL, Predilute	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3296	ATRX MMab, 0.1mL, Concentrate	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3297	ATRX MMab, 0.5mL, Concentrate	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3298	ATRX MMab, 1mL, Concentrate	MMab	BSB-108	IgG2a/K	PI 3298
BSB 3299	ATRX MMab, 5 + control Slides				
BSB 3300	Tinto BAP1 MMab, 3 ml, predilute	MMab	BSB-109	IgG1/K	PI 3305
BSB 3301	Tinto BAP1 MMab, 7 ml, predilute	MMab	BSB-109	IgG1/K	PI 3305
BSB 3302	Tinto BAP1 MMab, 15 ml, predilute	MMab	BSB-109	IgG1/K	PI 3305
BSB 3303	BAP1 MMab, 0.1 ml, concentrate	MMab	BSB-109	IgG1/K	PI 3305

Appendix A: List of Products, Bio SB

2017 New Antibodies

BSB 3304	BAP1 MMab, 0.5 ml, concentrate	MMab	BSB-109	IgG1/K	PI 3305
BSB 3305	BAP1 MMab, 1 ml, concentrate	MMab	BSB-109	IgG1/K	PI 3305
BSB 3306	BAP1 MMab, 5 + control slides				
BSB 3434	Tinto bcl6, 3mL, Predilute	MMab	BSB-26	IgG1	PI 3439
BSB 3435	Tinto bcl6, 7mL, Predilute	MMab	BSB-26	IgG1	PI 3439
BSB 3436	Tinto bcl6, 15mL, Predilute	MMab	BSB-26	IgG1	PI 3439
BSB 3437	bcl6, 0.1mL, Concentrate	MMab	BSB-26	IgG1	PI 3439
BSB 3438	bcl6, 0.5mL, Concentrate	MMab	BSB-26	IgG1	PI 3439
BSB 3439	bcl6, 1mL, Concentrate	MMab	BSB-26	IgG1	PI 3439
BSB 3440	bcl6, 5 + control Slides				
BSB 3307	Tinto Brachyury, 3mL, Predilute	RPab	Polyclonal	IgG	PI 3312
BSB 3308	Tinto Brachyury, 7mL, Predilute	RPab	Polyclonal	IgG	PI 3312
BSB 3309	Tinto Brachyury, 15mL, Predilute	RPab	Polyclonal	IgG	PI 3312
BSB 3310	Brachyury, 0.1mL, Concentrate	RPab	Polyclonal	IgG	PI 3312
BSB 3311	Brachyury, 0.5mL, Concentrate	RPab	Polyclonal	IgG	PI 3312
BSB 3312	Brachyury, 1mL, Concentrate	RPab	Polyclonal	IgG	PI 3312
BSB 3313	Brachyury, 5 + control Slides				
BSB 3314	Tinto Caveolin-1 RMab, 3 ml, predilute	RMab	EP353	IgG	PI 3319
BSB 3315	Tinto Caveolin-1 RMab, 7 ml, predilute	RMab	EP353	IgG	PI 3319
BSB 3316	Tinto Caveolin-1 RMab, 15 ml, predilute	RMab	EP353	IgG	PI 3319
BSB 3317	Caveolin-1 RMab, 0.1 ml, concentrate	RMab	EP353	IgG	PI 3319
BSB 3318	Caveolin-1 RMab, 0.5 ml, concentrate	RMab	EP353	IgG	PI 3319
BSB 3319	Caveolin-1 RMab 1 ml, concentrate	RMab	EP353	IgG	PI 3319
BSB 3320	Caveolin-1 RMab, 5 + control slides				
BSB 3321	Tinto CD16 RMab, 3mL, Predilute	RMab	EP364	IgG	PI 3326
BSB 3322	Tinto CD16 RMab, 7mL, Predilute	RMab	EP364	IgG	PI 3326
BSB 3323	Tinto CD16 RMab, 15mL, Predilute	RMab	EP364	IgG	PI 3326

Appendix A: List of Products, Bio SB

2017 New Antibodies

BSB 3324	CD16 RMab, 0.1mL, Concentrate	RMab	EP364	IgG	PI 3326
BSB 3325	CD16 RMab, 0.5mL, Concentrate	RMab	EP364	IgG	PI 3326
BSB 3326	CD16 RMab, 1mL, Concentrate	RMab	EP364	IgG	PI 3326
BSB 3327	CD16 RMab, 5 + control Slides				
BSB 3448	Tinto CD33 RMab, 3 ml, predilute	RMab	RBT-CD33	IgG	PI 3453
BSB 3449	Tinto CD33 RMab, 7 ml, predilute	RMab	RBT-CD33	IgG	PI 3453
BSB 3450	Tinto CD33 RMab, 15 ml, predilute	RMab	RBT-CD33	IgG	PI 3453
BSB 3451	CD33 RMab, 0.1 ml, concentrate	RMab	RBT-CD33	IgG	PI 3453
BSB 3452	CD33 RMab, 0.5 ml, concentrate	RMab	RBT-CD33	IgG	PI 3453
BSB 3453	CD33 RMab, 1 ml, concentrate	RMab	RBT-CD33	IgG	PI 3453
BSB 3454	CD33 RMab, 5 + control slides				
BSB 3328	Tinto GATA3 RMab, 3mL, Predilute	RMab	EP368	IgG	PI 3333
BSB 3329	Tinto GATA3 RMab, 7mL, Predilute	RMab	EP368	IgG	PI 3333
BSB 3330	Tinto GATA3 RMab, 15mL, Predilute	RMab	EP368	IgG	PI 3333
BSB 3331	GATA3 RMab, 0.1mL, Concentrate	RMab	EP368	IgG	PI 3333
BSB 3332	GATA3 RMab, 0.5mL, Concentrate	RMab	EP368	IgG	PI 3333
BSB 3333	GATA3 RMab, 1mL, Concentrate	RMab	EP368	IgG	PI 3333
BSB 3334	GATA3 RMab, 5 + control Slides				
BSB 3335	Tinto GH MMab, 3 ml, predilute	MMab	BSB-99	IgG1/K	PI 3340
BSB 3336	Tinto GH MMab, 7 ml, predilute	MMab	BSB-99	IgG1/K	PI 3340
BSB 3337	Tinto GH MMab, 15 ml, predilute	MMab	BSB-99	IgG1/K	PI 3340
BSB 3338	GH, 0.1 ml MMab, concentrate	MMab	BSB-99	IgG1/K	PI 3340
BSB 3339	GH, 0.5 ml MMab, concentrate	MMab	BSB-99	IgG1/K	PI 3340
BSB 3340	GH, 1 ml MMab, concentrate	MMab	BSB-99	IgG1/K	PI 3340
BSB 3341	GH MMab, 5 + control slides				
BSB 3342	Tinto Glucagon MMab, 3 ml, predilute	MMab	BSB-111	IgG1/K	PI 3347
BSB 3343	Tinto Glucagon MMab, 7 ml, predilute	MMab	BSB-111	IgG1/K	PI 3347

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BSB 3344	Tinto Glucagon MMab, 15 ml, predilute	MMab	BSB-111	IgG1/K	PI 3347
BSB 3345	Glucagon MMab, 0.1 ml, concentrate	MMab	BSB-111	IgG1/K	PI 3347
BSB 3346	Glucagon MMab, 0.5 ml, concentrate	MMab	BSB-111	IgG1/K	PI 3347
BSB 3347	Glucagon MMab, 1 ml, concentrate	MMab	BSB-111	IgG1/K	PI 3347
BSB 3348	Glucagon MMab, 5 + control slides				
BSB 3349	Tinto HE4 RMab, 3 ml, predilute	RMab	EP370	IgG	PI 3354
BSB 3350	Tinto HE4 RMab, 7 ml, predilute	RMab	EP370	IgG	PI 3354
BSB 3351	Tinto HE4 RMab, 15 ml, predilute	RMab	EP370	IgG	PI 3354
BSB 3352	HE4 RMab, 0.1 ml, concentrate	RMab	EP370	IgG	PI 3354
BSB 3353	HE4 RMab, 0.5 ml, concentrate	RMab	EP370	IgG	PI 3354
BSB 3354	HE4 RMab, 1 ml, concentrate	RMab	EP370	IgG	PI 3354
BSB 3355	HE4 RMab, 5 + control slides				
BSB 3356	Tinto Inhibin alpha RMab, 3 ml, predilute	RMab	EP378	IgG	PI 3361
BSB 3357	Tinto Inhibin alpha RMab, 7 ml, predilute	RMab	EP378	IgG	PI 3361
BSB 3358	Tinto Inhibin alpha RMab, 15 ml, predilute	RMab	EP378	IgG	PI 3361
BSB 3359	Inhibin alpha RMab, 0.1 ml, concentrate	RMab	EP378	IgG	PI 3361
BSB 3360	Inhibin alpha RMab, 0.5 ml, concentrate	RMab	EP378	IgG	PI 3361
BSB 3361	Inhibin alpha RMab, 1 ml, concentrate	RMab	EP378	IgG	PI 3361
BSB 3362	Inhibin alpha RMab, 5 + control slides				
BSB 3363	Tinto LAG-3 / CD223 RMab, 3 ml, predilute	RMab	EP294	IgG	PI 3368
BSB 3364	Tinto LAG-3 / CD223 RMab, 7 ml, predilute	RMab	EP294	IgG	PI 3368
BSB 3365	Tinto LAG-3 / CD223 RMab, 15 ml, predilute	RMab	EP294	IgG	PI 3368
BSB 3366	LAG-3 / CD223 RMab, 0.1 ml, concentrate	RMab	EP294	IgG	PI 3368
BSB 3367	LAG-3 / CD223 RMab, 0.5 ml, concentrate	RMab	EP294	IgG	PI 3368
BSB 3368	LAG-3 / CD223 RMab, 1 ml, concentrate	RMab	EP294	IgG	PI 3368
BSB 3369	LAG-3 / CD223 RMab, 5 + control slides				
BSB 3370	Tinto Langerin / CD207 RMab, 3 ml, predilute	RMab	EP349	IgG	PI 3375

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BSB 3371	Tinto Langerin / CD207 RMab, 7 ml, predilute	RMab	EP349	IgG	PI 3375
BSB 3372	Tinto Langerin / CD207 RMab, 15 ml, predilute	RMab	EP349	IgG	PI 3375
BSB 3373	Langerin / CD207 RMab, 0.1 ml, concentrate	RMab	EP349	IgG	PI 3375
BSB 3374	Langerin / CD207 RMab, 0.5 ml, concentrate	RMab	EP349	IgG	PI 3375
BSB 3375	Langerin / CD207 RMab, 1 ml, concentrate	RMab	EP349	IgG	PI 3375
BSB 3376	Langerin / CD207 RMab, 5 + control slides				
BSB 3377	Tinto LEF-1 RMab, 3 ml, predilute	RMab	EP310	IgG	PI 3382
BSB 3378	Tinto LEF-1 RMab, 7 ml, predilute	RMab	EP310	IgG	PI 3382
BSB 3379	Tinto LEF-1 RMab, 15 ml, predilute	RMab	EP310	IgG	PI 3382
BSB 3380	LEF-1 RMab, 0.1 ml, concentrate	RMab	EP310	IgG	PI 3382
BSB 3381	LEF-1 RMab, 0.5 ml, concentrate	RMab	EP310	IgG	PI 3382
BSB 3382	LEF-1 RMab, 1 ml, concentrate	RMab	EP310	IgG	PI 3382
BSB 3383	LEF-1 RMab, 5 + control slides				
BSB 3455	Tinto Mesothelial Cell, 3 ml, predilute	MMab	HBME-1	IgM/K	PI 3460
BSB 3456	Tinto Mesothelial Cell, 7 ml, predilute	MMab	HBME-1	IgM/K	PI 3460
BSB 3457	Tinto Mesothelial Cell, 15 ml, predilute	MMab	HBME-1	IgM/K	PI 3460
BSB 3458	Mesothelial Cell, 0.1 ml, concentrate	MMab	HBME-1	IgM/K	PI 3460
BSB 3459	Mesothelial Cell, 0.5 ml, concentrate	MMab	HBME-1	IgM/K	PI 3460
BSB 3460	Mesothelial Cell, 1 ml, concentrate	MMab	HBME-1	IgM/K	PI 3460
BSB 3461	Mesothelial Cell, 5 + control slides				
BSB 3384	Tinto Myoglobin MMab, 3 ml, predilute	MMab	BSB-104	IgG1	PI 3389
BSB 3385	Tinto Myoglobin MMab, 7 ml, predilute	MMab	BSB-104	IgG1	PI 3389
BSB 3386	Tinto Myoglobin MMab, 15 ml, predilute	MMab	BSB-104	IgG1	PI 3389
BSB 3387	Myoglobin MMab, 0.1 ml, concentrate	MMab	BSB-104	IgG1	PI 3389
BSB 3388	Myoglobin MMab, 0.5 ml, concentrate	MMab	BSB-104	IgG1	PI 3389
BSB 3389	Myoglobin MMab, 1 ml, concentrate	MMab	BSB-104	IgG1	PI 3389
BSB 3390	Myoglobin MMab, 5 + control slides				

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2017 New Antibodies

BSB 3392	Tinto Napsin A MMab, 3 ml, predilute	MMab	BSB-112	IgG1/K	PI 3397
BSB 3393	Tinto Napsin A MMab, 7 ml, predilute	MMab	BSB-112	IgG1/K	PI 3397
BSB 3394	Tinto Napsin A MMab, 15 ml, predilute	MMab	BSB-112	IgG1/K	PI 3397
BSB 3395	Napsin A MMab, 0.1 ml, concentrate	MMab	BSB-112	IgG1/K	PI 3397
BSB 3396	Napsin A MMab, 0.5 ml, concentrate	MMab	BSB-112	IgG1/K	PI 3397
BSB 3397	Napsin A MMab, 1 ml, concentrate	MMab	BSB-112	IgG1/K	PI 3397
BSB 3398	Napsin A MMab, 5 + control slides				
BSB 3406	Tinto Parvalbumin RMab, 3 ml, predilute	RMab	EP300	IgG	PI 3411
BSB 3407	Tinto Parvalbumin RMab, 7 ml, predilute	RMab	EP300	IgG	PI 3411
BSB 3408	Tinto Parvalbumin RMab, 15 ml, predilute	RMab	EP300	IgG	PI 3411
BSB 3409	Parvalbumin RMab, 0.1 ml, concentrate	RMab	EP300	IgG	PI 3411
BSB 3410	Parvalbumin RMab, 0.5 ml, concentrate	RMab	EP300	IgG	PI 3411
BSB 3411	Parvalbumin RMab, 1 ml, concentrate	RMab	EP300	IgG	PI 3411
BSB 3412	Parvalbumin RMab, 5 + control slides				
BSB 3399	Tinto SMAD4/DPC4 RMab, 3mL, Predilute	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3400	Tinto SMAD4/DPC4 RMab, 7mL, Predilute	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3401	Tinto SMAD4/DPC4 RMab, 15mL, Predilute	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3402	SMAD4/DPC4 RMab, 0.1mL, Concentrate	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3403	SMAD4/DPC4 RMab, 0.5mL, Concentrate	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3404	SMAD4/DPC4 RMab, 1mL, Concentrate	RMab	RBT-SMAD4	IgG	PI 3404
BSB 3405	SMAD4/DPC4 RMab, 5 + control Slides				
BSB 3413	Tinto Somatostatin MMab, 3 ml, predilute	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3414	Tinto Somatostatin MMab, 7 ml, predilute	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3415	Tinto Somatostatin MMab, 15 ml, predilute	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3416	Somatostatin MMab, 0.1 ml, concentrate	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3417	Somatostatin MMab, 0.5 ml, concentrate	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3418	Somatostatin MMab, 1 ml, concentrate	MMab	BSB-113	IgG2a/K	PI 3418
BSB 3419	Somatostatin MMab, 5 + control slides				

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2017 New Antibodies

BSB 3420	Tinto STAT6 RMab, 3mL, Predilute	RMab	EP325	IgG	PI 3425
BSB 3421	Tinto STAT6 RMab, 7mL, Predilute	RMab	EP325	IgG	PI 3425
BSB 3422	Tinto STAT6 RMab, 15mL, Predilute	RMab	EP325	IgG	PI 3425
BSB 3423	STAT6 RMab, 0.1mL, Concentrate	RMab	EP325	IgG	PI 3425
BSB 3424	STAT6 RMab, 0.5mL, Concentrate	RMab	EP325	IgG	PI 3425
BSB 3425	STAT6 RMab, 1mL, Concentrate	RMab	EP325	IgG	PI 3425
BSB 3426	STAT6 RMab, 5 + control Slides				
BSB 3427	Tinto Tau MMAB, 3 ml, predilute	MMab	BSB-115	IgG1/K	PI 3432
BSB 3428	Tinto Tau MMAB, 7 ml, predilute	MMab	BSB-115	IgG1/K	PI 3432
BSB 3429	Tinto Tau MMAB, 15 ml, predilute	MMab	BSB-115	IgG1/K	PI 3432
BSB 3430	Tau MMAB, 0.1 ml, concentrate	MMab	BSB-115	IgG1/K	PI 3432
BSB 3431	Tau MMAB, 0.5 ml, concentrate	MMab	BSB-115	IgG1/K	PI 3432
BSB 3432	Tau MMAB, 1 ml, concentrate	MMab	BSB-115	IgG1/K	PI 3432
BSB 3433	Tau MMAB, 5 + control slides				