Compliance Report

Applicant:	Biologix Plastics (Changzhou) Co., Ltd.
Address:	LinChang Village, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu Province 213141, P.R. China.
Product:	See annex for details
Type:	See annex for details
Product Classification:	Others

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **03069**
Initial Issue Date: **30 May 2019**

Tony Chen

General Manager (Signature)

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Annex to Report (No. 03069)

Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Centrifuge Tubes	10-9151, 10-9152, 10-9501, 10-9502, 10-9815, 10-9850, 10-0151, 10-0152, 10-0501, 10-0502, 10-0815, 10-0850, 10-0122, 10-0123
Microcentrifuge Tubes	80-1500, 80-1501, 80-1502, 80-1503, 80-0015, 80-0500, 80-0020
Test Tubes and Caps	12-1275, 12-2275, 12-1300, 12-1299, 12-1399
Screw Cap Microtubes and Caps	81-0053, 81-0054, 81-0153, 81-0154, 81-0203, 81-0204, 81-0000, 81-0001, 81-0002, 81-0003, 81-0004, 81-0005, 10-0101, 10-0082, 10-0052, 10-0000, 82-7215, 82-7216, 82-7217, 82-7218, 82-7219, 82-7115, 82-7116, 82-7117, 82-7118, 82-7119, 82-7054, 82-7055, 82-7056, 82-7057, 82-7058, 82-7059, 82-7060, 82-7061, 82-7153, 82-7162, 82-7163, 82-7164, 82-7165, 82-7166, 82-7167, 82-7168, 82-7154, 82-7155, 82-7156, 82-7157, 82-7158, 82-7159, 82-7160, 82-7161, 82-7204, 82-7205, 82-7206, 82-7207, 82-7208, 82-7209, 82-7210, 82-7211, 81-0055, 81-0056, 81-0006
Cryogenic Vials	81-7053, 81-7054, 81-7153, 81-7154, 81-7203, 81-7204, 81-8053, 81-8054, 81-8153, 81-8154, 81-8203, 81-8204, 81-7055, 81-7056, 81-7205, 88-6210, 88-6211, 88-6212, 88-6213, 88-6214, 88-6215, 88-6216, 88-6217, 88-6200, 88-6201, 88-6202, 88-6203, 88-6204, 88-6205, 88-6206, 88-6207, 88-6500, 88-6501, 88-6502, 88-6503, 88-6504, 88-6505, 88-6506, 88-6507, 88-6000, 88-6001, 88-6002, 88-6003, 88-6004, 88-6005, 88-6006, 88-6007, 88-3210, 88-3211, 88-3212, 88-3213, 88-3214, 88-3215, 88-3216, 88-3217, 88-3200, 88-3201, 88-3202, 88-3203, 88-3204,88-3205, 88-3206, 88-3207, 88-3500, 88-3501, 88-3502, 88-3503, 88-3504, 88-3505, 88-3506, 88-3507
PCR Tubes & Plates	60-0082, 60-0182, 60-0282, 60-0382, 60-0482, 60-0002, 60-0102, 60-0202, 60-0302, 60-0402, 60-0008, 60-0108, 60-0208, 60-0308, 60-0408, 60-0088, 60-0188, 60-0288, 60-0388, 60-0488, 60-0056, 60-0156, 60-0256, 60-0356, 60-0456

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Annex to Report (No. 03069)

Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Pipet Tips	20-0010, 20-0200, 20-1000, 21-0010, 21-0200, 21-1000, 20-1250, 21-1250, 20-1251
Transfer Pipets	30-0135, 30-0135A1, 30-0135B20, 30-0138,30-0138A1, 30-0138B20, 30-0238A1
Tri-Cornered Beakers	93-0050, 93-0100, 93-0250, 93-0400, 93-0800, 93-1000
Solution Basins	25-0052, 25-0051, 25-1202, 25-1025, 25-1100, 25-1202
Microtube Racks	90-8009, 90-1550, 90-5025
Plastic Cryogenic Storage Boxes	90-9009, 90-9250, 90-9081, 90-9100, 90-9025, 90-9210, 90-9200, 90-9381
Cardboard Freezer Boxes	90-1281, 90-1200, 90-1381, 90-1300, 90-2281, 90-2200, 90-2381, 90-2300, 90-6281, 90-6200, 90-1536, 90-5016, 90-5281, 90-5200, 90-6100, 90-1100, 90-1100, 90-8281, 90-8200, 90-8100, 90-8381
Cell Scrapers & Lifters	70-1180, 70-1250, 70-2180
Cell Strainers	15-1040, 15-1070, 15-1100
Slide Storage Boxes	41-5025, 41-5100, 41-6025, 41-6100, 7101, 7105
Slide Mailers	41-4001, 41-4002, 41-4020
Drosophila Vials	51-0500, 51-0501, 51-0800, 51-0801
Drosophila Bottles	51-17720, 51-17721
Petri Dishes	66-1501, 66-1560, 66-1515, 66-1701
Inoculating Loops & Needles	65-0001, 65-0010, 65-0002
Product Name	Type
Cell Spreaders	65-1001,65-1010
Stainless Steel Freezer Racks	99-1224, 99-1220, 99-1216, 99-2224, 99-2220, 99-2216, 99-2215, 99-2212, 99-5220, 99-5216, 99-5215, 99-5212, 99-1132, 99-1128, 99-1124, 99-2132, 99-2128, 99-2124, 99-2120, 99-2121, 99-2118, 99-6207, 99-6209, 99-6210, 99-6212, 99-6213, 99-7220, 99-7224, 99-7216, 99-7132, 99-7128, 99-7124, 99-2230, 99-6206, 99-6208, 99-6211, 96-2118, 96-2121, 96-2120, 96-2124, 96-2128, 96-2132, 96-2212, 96-2215, 96-2216, 96-2220, 96-2224, 96-2230, 96-6206, 96-6207, 96-6208, 96-6209, 96-6210, 96-6211, 96-6212, 96-6213, 96-1216, 96-1220, 96-1224, 96-1124, 96-1128, 96-1132, 96-7216, 96-7220, 96-7224, 96-7124, 96-7128, 96-7132

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Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
CryoKING Cryogenic Vials	88-0050,88-0051,88-0052,88-0053,88-0054,88-0055, 88-0100, 88-0101, 88-0102, 88-0103, 88-0104, 88-0105, 88-0150, 88-0151, 88-0152, 88-0153, 88-0154, 88-0155, 88-1050, 88-1051, 88-1052,88-1053, 88-1054, 88-1055, 88-1100, 88-1101, 88-1102, 88-1103, 88-1104, 88-1105, 88-1150, 88-1151, 88-1152, 88-1153, 88-1154, 88-1155, 88-0056, 88-0057, 88-0106, 88-0107, 88-0156, 88-0157, 88-0200, 88-0201, 88-0202, 88-0203, 8-0204, 88-0205, 88-0206, 88-0207, 88-0210, 88-0211, 88-0212, 88-0213, 88-0214, 88-0215, 88-0216, 88-0217, 88-0500, 88-0501, 88-0502, 88-0503, 88-0504, 88-0505, 88-0506, 88-0507, 88-1056, 88-1057, 88-1106, 88-1107, 88-1156, 88-1157, 88-1200, 88-1201, 88-1202, 88-1203, 88-1204, 88-1205, 88-1206, 88-1207, 88-1210, 88-1211, 88-1212, 88-1213, 88-1214, 88-1215, 88-1216, 88-1217, 88-1500, 88-1501, 88-1502, 88-1503, 88-1504, 88-1505, 88-1506, 88-1507, 88-6050, 88-6051, 88-6052, 88-6053, 88-6054, 88-6055, 88-6056, 88-6057, 88-6100, 88-6101, 88-6102, 88-6103, 88-6104, 88-6105, 88-6106, 88-6107, 88-6150, 88-6151, 88-6152, 88-6153, 88-6154, 88-6155, 88-6156, 88-6157, 88-7200, 88-7201, 88-7202, 88-7203, 88-7204, 88-7205, 88-7206, 88-7207, 88-7210, 88-7211, 88-7212, 88-7213, 88-7214, 88-7215, 88-7216, 88-7217, 88-7500, 88-7501, 88-7502, 88-7503, 88-7504, 88-7505, 88-7506, 88-7507, 88-9050, 88-9051, 88-9052,88-9053, 88-9054,88-9055, 88-9056, 88-9057, 88-9100, 88-9101, 88-9102, 88-9103, 88-9104, 88-9105, 88-9106, 88-9107, 88-9150, 88-9151, 88-9152, 88-9153, 88-9154, 88-9155, 88-9156, 88-9157, 88-9200, 88-9201, 88-9202, 88-9203, 88-9204, 88-9205, 88-9206, 88-9207, 88-9210, 88-9211, 88-9212, 88-9213, 88-9214, 88-9215, 88-9216, 88-9217, 88-9500, 88-9501, 88-9502, 88-9503, 88-9504, 88-9505, 88-9506, 88-9507, 88-4030, 88-4031, 88-4032, 88-4033, 88-4034, 88-4035, 88-4036, 88-4037, 88-4050, 88-4051, 88-4052, 88-4053, 88-4054, 88-4055, 88-4056, 88-4057, 88-4080, 88-4081, 88-4082, 88-4083, 88-4084, 88-4085, 88-4086, 88-4087, 88-4100, 88-4101, 88-4102, 88-4103, 88-4104, 88-4105, 88-4106, 88-4107, 88-4210, 88-4211, 88-4212, 88-4213, 88-4214, 88-4215, 88-4216, 88-4217, 88-4200, 88-4201, 88-4202, 88-4203, 88-4204, 88-4205, 88-4206, 88-4207, 88-4500, 88-4501, 88-4502, 88-4503, 88-4504, 88-4505, 88-4506, 88-4507

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Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
PC Cryogenic Boxes	98-0113, 98-0213, 98-0313, 98-0200, 98-0213, 98-4217, 98-4317, 98-4417, 98-4117, 98-4127, 98-4227
CryoKING Combo	89-3050, 89-3051, 89-3052, 89-3053, 89-3054, 89-3055, 89-3100, 89-3101, 89-3102, 89-3103, 89-3104, 89-3105, 89-3150, 89-3151, 89-3152, 89-3153, 89-3154, 89-3155, 89-3056 , 89-3057, 89-3106, 89-3107, 89-3156, 89-3157, 89-3200, 89-3201, 89-3202, 89-3203, 89-3204, 89-3205, 89-3206, 89-3207, 89-3210, 89-3211, 89-3212, 89-3213, 89-3214, 89-3215, 89-3216, 89-3217, 89-3500, 89-3501, 89-3502, 89-3503, 89-3504, 89-3505, 89-3506, 89-3507, 89-4820, 89-4821, 89-4822, 89-4823, 89-4824, 89-4825, 89-4826, 89-4827, 89-4850, 89-4851, 89-4852, 89-4853, 89-4854, 89-4855, 89-4856, 89-4857, 89-9050, 89-9051, 89-9052, 89-9053, 89-9054, 89-9055, 89-9056, 89-9057, 89-9100, 89-9101, 89-9102, 89-9103, 89-9104, 89-9105, 89-9106, 89-9107, 89-9150, 89-9151, 89-9152, 89-9153, 89-9154, 89-9155, 89-9156, 89-9157, 89-9200, 89-9201, 89-9202, 89-9203, 89-9204, 89-9205, 89-9206, 89-9207, 89-9210, 89-9211, 89-9212, 89-9213, 89-9214, 89-9215, 89-9216, 89-9217, 89-9500, 89-9501, 89-9502, 89-9503, 89-9504, 89-9505, 89-9506, 89-9507, 89-4030, 89-4031, 89-4032, 89-4033, 89-4034, 89-4035, 89-4036, 89-4037 , 89-4050, 89-4051, 89-4052, 89-4053, 89-4054, 89-4055, 89-4056, 89-4057, 89-4080, 89-4081, 89-4082, 89-4083, 89-4084, 89-4085, 89-4086, 89-4087, 89-4100, 89-4101, 89-4102, 89-4103, 89-4104, 89-4105, 89-4106, 89-4107, 89-4920, 89-4921, 89-4922, 89-4923, 89-4924, 89-4925, 89-4926, 89-4927, 89-4420, 89-4421, 89-4422, 89-4423, 89-4424, 89-4425, 89-4426, 89-4427, 89-4450, 89-4451, 89-4452, 89-4453, 89-4454, 89-4455, 89-4456, 89-4457, 89-4230, 89-4231, 89-4232, 89-4233, 89-4234, 89-4235, 89-4236, 89-4237, 89-4250, 89-4251, 89-4252, 89-4253, 89-4254, 89-4255, 89-4256 , 89-4257, 89-4280, 89-4281, 89-4282, 89-4283, 89-4284, 89-4285, 89-4286, 89-4287, 89-4210, 89-4211, 89-4212, 89-4213, 89-4214, 89-4215, 89-4216, 89-4217
Funnels	35-6050
Drosophila Plugs	51-0505, 51-0805, 51-17725
Cell Culture Flasks	07-8025, 07-8075, 07-8175, 07-9025, 07-9075, 07-9175
Cell Culture Dishes	07-3035, 07-3060, 07-3100, 07-3150

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Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Cell Culture Plates	07-6006, 07-6012, 07-6024, 07-6048, 07-6096
Serological Pipettes	07-5001, 07-5002, 07-5005, 07-5010, 07-5025, 07-5050
Filter Tips	22-0010, 22-0011, 23-0010, 23-0011, 22-0200, 22-0201, 23-0200, 23-0201, 22-1000, 22-1001, 23-1000, 23-1001
Deep-well Plates	02-1016, 02-1022, 02-2010
Reagent Bottles	04-2008, 04-3008, 04-2015, 04-3015, 04-2030, 04-3030, 04-2060, 04-3060, 04-2125, 04-3125, 04-2250, 04-3250, 04-2500, 04-3500, 04-2100, 04-3100, 04-0005, 04-1005, 04-0010, 04-1010, 04-0015, 04-1015, 04-0030, 04-1030,04-0060, 04-1060, 04-0125, 04-1125, 04-0200, 04-1200, 04-0250, 04-1250, 04-0500, 04-1500
Gloves	97-1111, 97-1112, 97-1113, 97-1114, 97-1115, 97-6111, 97-6112, 97-6113, 97-6114, 97-6115
Sealing Films	61-0010, 61-0110, 61-0013, 61-0012, 61-0015, 61-0014, 61-0011, 61-0120, 61-0121, 61-0125, 61-0030, 61-0031, 61-0040, 61-0041, 61-0210, 61-0250, 61-0020, 61-0025, 61-0080, 61-0081, 61-0145, 61-0050, 61-0051, 61-0152, 61-0153, 61-0060, 61-0061, 61-0070, 61-0071, 61-0072, 61-0301, 61-0302, 61-0303, 61-0304, 61-0130, 61-0131, 61-0132, 61-0410, 61-0411
Waste Fluid Collection System	05-2720, 05-2721, 05-2791, 05-2792, 05-2793, 05-2794, 05-2797, 05-2798
Cell Culture Slides	07-2101, 07-2102, 07-2104, 07-2108

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