

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1632686**

Certificate Holder: **Biologix Plastics (Changzhou) Co., Ltd.**
Unified Social Credit Code: 91320404666358586K
Registration Address: Linchang Village, Zouqu Town, Zhonglou District, Changzhou City, 213141 Jiangsu, P. R. China
Operation Address: No. 45, East Changjin Road, Zouqu Town, Zhonglou District, Changzhou City, 213141 Jiangsu, P. R. China

Scope: Manufacturing of Plastic Consumables for Laboratory and Medical Treatment

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-04-21 until 2025-04-20.
It remains valid subject to satisfactory surveillance audits.
First certification 2016
This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2022-03-27


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free Trade Zone), 100176, P. R. China



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: 31 Jan 2021

Tony Chen

General Manager (Signature)



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 10-9052-RO, 10-9082-RO, 10-0082-Y, 10-0101-Y, 10-9502E
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, 81-0204S, 81-0000S
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, 81-7204-DB 81-7154-DB 81-7204-GB 88-3200S 88-3201S 88-3202S 88-3203S 88-3204S 88-3205S 88-3206S 88-3207S 88-3500S 88-3501S 88-3502S 88-3503S 88-3504S 88-3505S 88-3506S 88-3507S 88-6200S 88-6201S 88-6202S 88-6203S 88-6204S 88-6205S 88-6206S 88-6207S 88-6500S 88-6501S 88-6502S 88-6503S 88-6504S 88-6505S 88-6506S 88-6507S
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

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.



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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Annex to Report (No. 03069)

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, 19-0001S
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, 23-0010A, 23-0010H, 23-0011H, 23-0011S, 23-0020A, 23-0021S, 23-0051S, 23-0100A, 23-0101S, 23-0200A, 23-0200A1, 23-0200A2, 23-0200H, 23-0201H, 23-0201S, 23-1000A, 23-1000H, 23-1001A, 23-1001S, 23-1250H, 23-0010B, 23-0011B, 23-0200B, 23-0201B, 23-0100, 23-1010, 23-0010S, 23-0200S, R23-0020, R23-0200, R23-1000
Deep-well Plates	02-1016, 02-1022, 02-2010-50, 02-1116, 02-1216, 02-1316, 02-1122, 02-1222, 02-1322, 02-2110, 02-2210, 02-2310, 02-6022, 02-6122, 02-6222, 02-6322, 02-1022, 02-7122, 02-7222, 02-7322, 02-8005, 02-8105, 02-8205, 02-8305, 02-9010, 02-9110, 02-9210, 02-9310, 02-0096, 02-0196, 02-0008, 02-1096
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, 04-0005U, 04-1005U, 04-0010U, 04-1010U, 04-0015U, 04-1015U, 04-0030U, 04-1030U, 04-0060U, 04-1060U, 04-0125U, 04-1125U, 04-0200U, 04-1200U, 04-0250U, 04-1250U, 04-0500U, 04-1500U
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
Swab	RH-2018, RH-2019, 10028, 905101, 901101, 71-0121, 71-0122

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