

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)

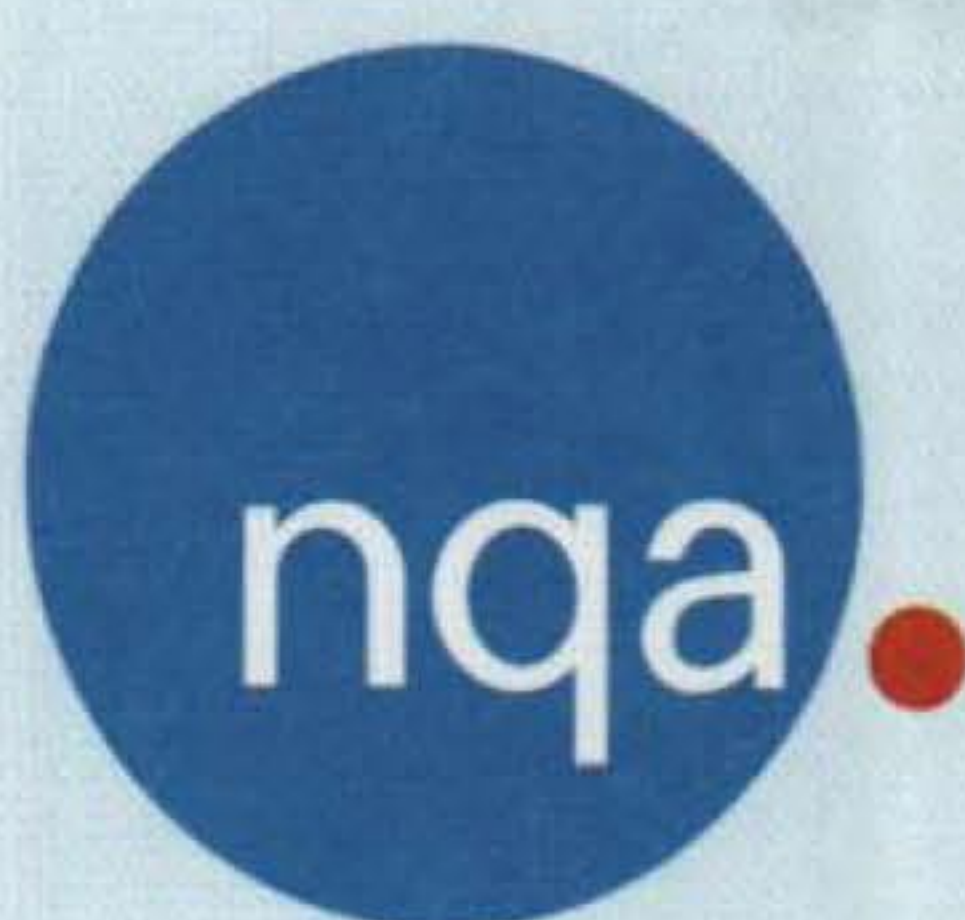


Annex to Report (No. 03069)

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
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.



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

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

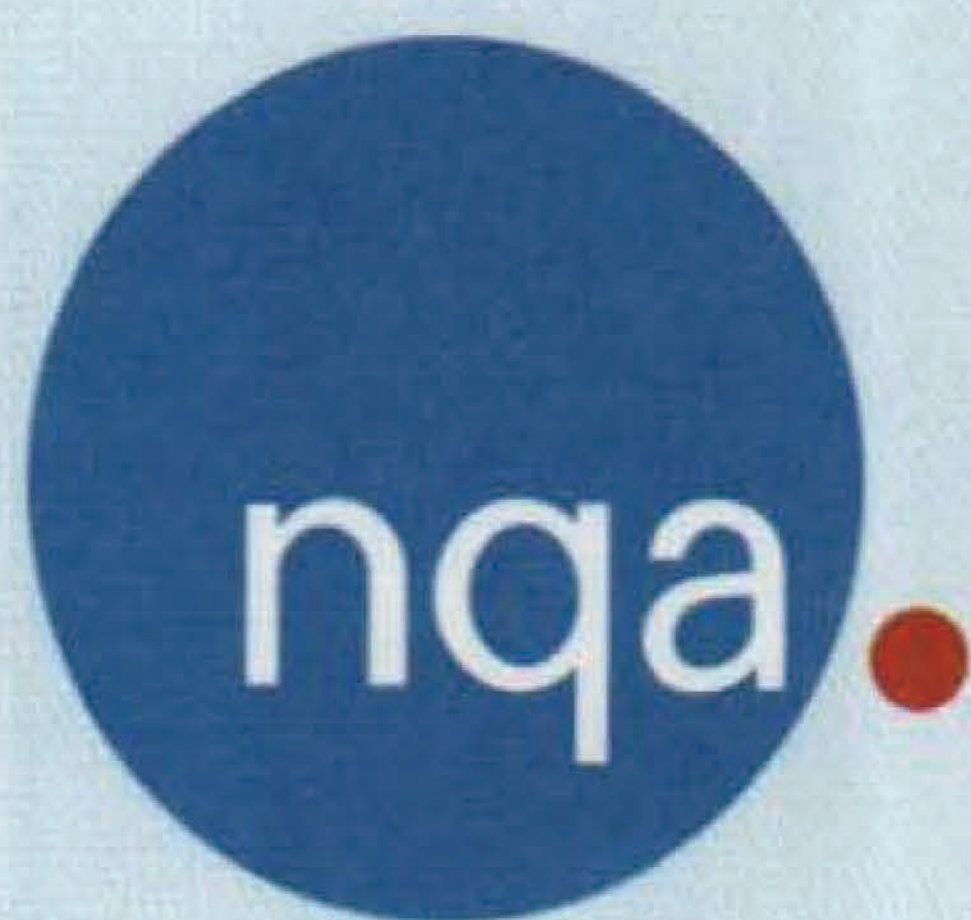


Annex to Report (No. 03069)

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

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



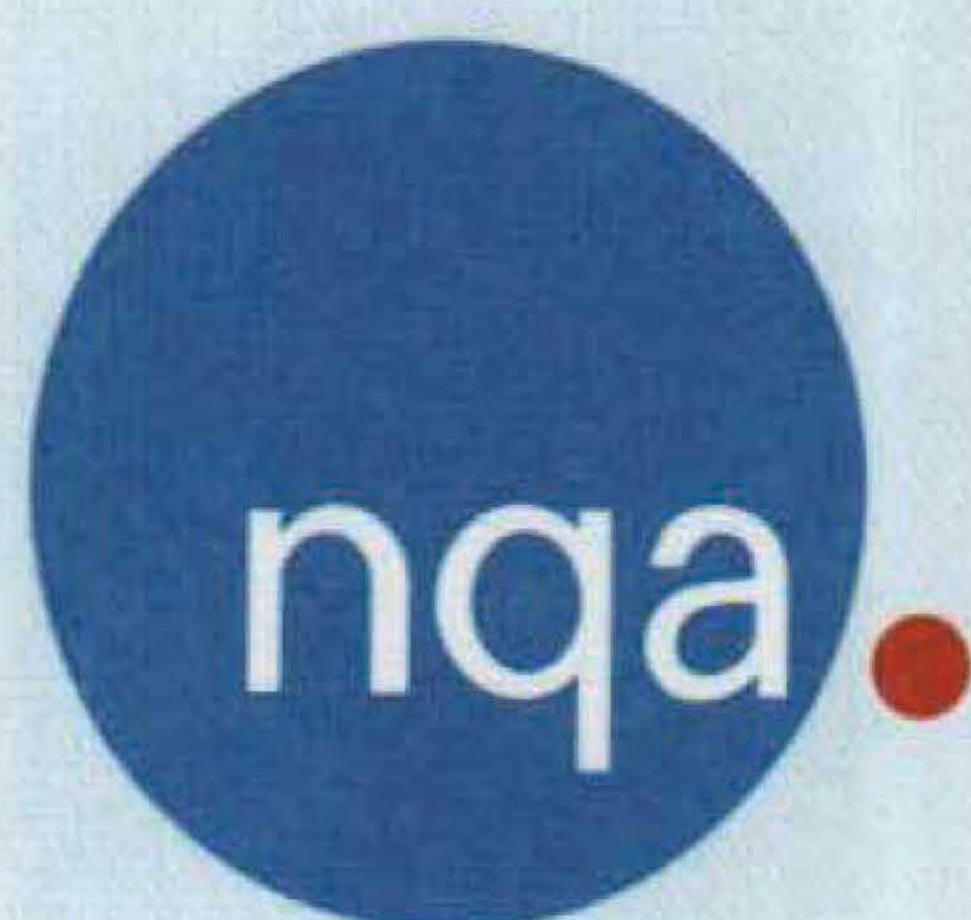
Annex to Report (No. 03069)

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

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
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
Deep-well Plates	02-1016, 02-1022, 02-2010, 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
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
Swab	RH-2018, RH-2019, 10028, 905101, 901101, 71-0121, 71-0122

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



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Datum: 9 mei 2022
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 25 april 2022 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Biologix Corporation met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Cell Culture Flasks
(geen merknaam) (NL-CA002-2022-69165)
Centrifuge Tubes
(geen merknaam) (NL-CA002-2022-69156)
Cryogenic Boxes
(geen merknaam) (NL-CA002-2022-69164)
Cryogenic Vials
(geen merknaam) (NL-CA002-2022-69163)
Deep Well Plates
(geen merknaam) (NL-CA002-2022-69160)
Pipet Tips
(geen merknaam) (NL-CA002-2022-69157)
Reagent Bottles
(geen merknaam) (NL-CA002-2022-69161)
Sealing Films
(geen merknaam) (NL-CA002-2022-69162)
Solution Basins
(geen merknaam) (NL-CA002-2022-69159)
Transfer Pipets
(geen merknaam) (NL-CA002-2022-69158)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20222921

Bijlagen

Uw aanvraag
25 april 2022

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en
het kenmerk van deze brief.*

ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel 10, eerste lid van Richtlijn 98/79/EG).

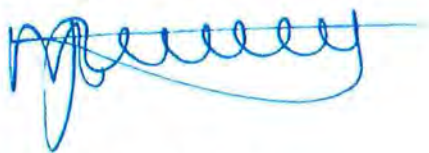
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Biologix Corporation de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit).

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse taaleisen zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Staatssecretaris van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde



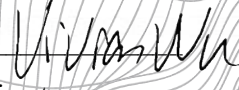
DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

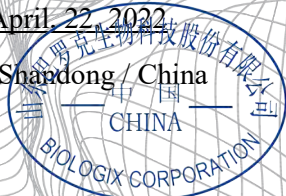
Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Cell Culture Flasks
Specification: 07-8025,07-8075,07-8175,07-9025,07-9075,07-9175
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April 22, 2022
Place: Shandong / China





DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Centrifuge Tubes
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Centrifuge Tubes	10-0151,10-0152,10-0501,10-0502,10-9151,10-9152,10-9501,10-9502,10-0815,10-0850,10-9815 10-9850,80-0015, 80-0015A,80-1500,80-1500-S,80-0500,80-0020,80-1501, 80-1502,80-1503



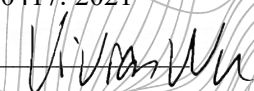
DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Cryogenic Boxes
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

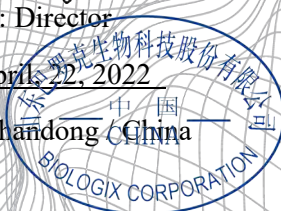
EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 

Position: Director

Date: April 22, 2022

Place: Shandong, China



Annex

Product Name	Model
Cryogenic Boxes	90-1200,90-1281,90-1300,90-1381,90-1536,90-5016,90-2200,90-2281,90-2300,90-2381,90-5200,90-5281,90-8100,90-8200,90-8281,90-8381,90-9009,90-9025,90-9081,90-9100,90-9200,90-9210,90-9250,90-9381,98-0113, 98-0213,98-1213,98-0200,98-0313,98-4127,98-4227,98-4117,98-4217,98-5327,90-1550,90-5025,90-8009, 41-4020,41-5025,41-5100,41-6025,41-6100



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Cryogenic Vials
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 

Position: Director

Date: April 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Cryogenic Vials	81-0053,81-0054,81-0153,81-0203,81-0055,81-0056,81-0154,81-0204,81-0205,81-0000,81-0001,81-0002,81-0003,81-0004,81-0005,81-0006,81-7055,81-7056,81-7154,81-7204,81-7205,81-8204,81-7053,81-7054,81-7153,81-7203,88-0050,88-0051,88-0052,88-0053,88-0054,88-0055,88-0057,88-0100,88-0101,88-0102,88-0103,88-0105,88-0105,88-0107,88-0150,88-0151,88-0152,88-0153,88-0154,88-0155,88-0157,88-0200,88-0201,88-0202,88-0203,88-0204,88-0205,88-0207,88-0210,88-0211,88-0212,88-0213,88-0214,88-0215,88-0217,88-0500,88-0501,88-0502,88-0503,88-0504,88-0505,88-0507,88-1050,88-1051,88-1052,88-1053,88-1054,88-1055,88-1057,88-1100,88-1101,88-1102,88-1103,88-1105,88-1105,88-1107,88-1150,88-1151,88-1152,88-1153,88-1154,88-1155,88-1157,88-1200,88-1201,88-1202,88-1203,88-1204,88-1205,88-1207,88-1210,88-1211,88-1212,88-1213,88-1214,88-1215,88-1217,88-1500,88-1501,88-1502,88-1503,88-1504,88-1505,88-1507,88-6050,88-6051,88-6052,88-6053,88-6054,88-6055,88-6057,88-6100,88-6101,88-6102,88-6103,88-6104,88-6105,88-6107,88-6150,88-6151,88-6152,88-6153,88-6154,88-6155,88-6157,88-7200,88-7201,88-7202,88-7203,88-7204,88-7205,88-7207,88-7210,88-7211,88-7212,88-7213,88-7214,88-7215,88-7217,88-7500,88-7501,88-7502,88-7503,88-7504,88-7505,88-7507,88-9050,88-9051,88-9052,88-9053,88-9054,88-9055,88-9057,88-9100,88-9101,88-9102,88-9103,88-9105,88-9105,88-9107,88-9150,88-9151,88-9152,88-9153,88-9154,88-9155,88-9157,88-9200,88-9201,88-9202,88-9203,88-9204,88-9205,88-9207,88-9210,88-9211,88-9212,88-9213,88-9214,88-9215,88-9217,88-9500,88-9501,88-9502,88-9503,88-9504,88-9505,88-9507,88-6200,88-6201,88-6202,88-6203,88-6204,88-6205,88-6207,88-6210,88-6211,88-6212,88-6213,88-6214,88-6215,88-6217,88-6200S,88-6201S,88-6202S,88-6203S,88-6204S,88-6205S,88-6207S,88-6500S,88-6501S,88-6502S,88-6503S,88-6504S,88-6505S,88-6507S,88-6500,88-6501,88-6502,88-6503,88-6504,88-6505,88-6507,88-3500,88-3501,88-3502,88-3503,88-3504,88-3505,88-3507,88-3200,88-3201,88-3202,88-3203,88-3204,88-3205,88-3207,88-3210,88-3211,88-3212,88-3213,88-3214,88-3215,88-3217,88-3500S,88-3501S,88-3502S,88-3503S,88-3504S,88-3505S,88-3507S,88-3200S,88-3201S,88-3202S,88-3203S,88-3204S,88-3205S,88-3207S, 88-4030, 88-4031,88-4033, 88-4034, 88-4035, 88-4037, 88-4050, 88-4051, 88-4052,88-4053, 88-4054, 88-4055, 88-4057, 88-4080, 88-4081, 88-4082,88-4083, 88-4084, 88-4085, 88-4087, 88-4100, 88-4101, 88-4102,88-4103, 88-4104, 88-4105, 88-4107,88-5143,88-5141,88-5142,88-5145,88-5083,88-5081,88-5082,88-5085,89-9050,89-9051,89-9052,89-9053,89-

	9054,89-9055,89-9057,89-9100,89-9101,89-9102,89-9103,89-9104,89-9105,89-9107,89-9150,89-9151,89-9152,89-9153,89-9154,89-9155,89-9157,89-9200,89-9201,89-9202,89-9203,89-9204,89-9205,89-9207,89-3050,89-3051,89-3052,89-3053,89-3054,89-3055,89-3057,89-3100,89-3101,89-3102,89-3103,89-3104,89-3105,89-3107,89-3150,89-3151,89-3152,89-3153,89-3154,89-3155,89-3157,89-3202,89-3203,89-3204,89-3205,89-3207,89-4230, 89-4231, 89-4232,89-4233, 89-4234, 89-4235, 89-4237, 89-4250, 89-4251, 89-4252,89-4253, 89-4254, 89-4255, 89-4257, 89-4280, 89-4281, 89-4282,89-4283, 89-4284, 89-4285, 89-4287, 89-4210, 89-4211, 89-4212,89-4213, 89-4214, 89-4215, 89-4217, 89-4030, 89-4031, 89-4032,89-4033, 89-4034, 89-4035, 89-4037, 89-4050, 89-4051, 89-4052,89-4053, 89-4054, 89-4055, 89-4057, 89-4080, 89-4081, 89-4082,89-4083, 89-4084, 89-4085, 89-4087, 89-4100, 89-4101, 89-4102,89-4103, 89-4104, 89-4105, 89-4107,89-5143,89-5141,89-5142,89-5145,89-5083,89-5081,89-5082,89-5085,89-9500,89-9501,89-9502,89-9503,89-9504,89-9505,89-9507,89-9230,89-9231,89-9232,89-9233,89-9234,89-9235,89-9237,89-9220,89-9221,89-9222,89-9223,89-9224,89-9225,89-9227,89-9210,89-9211,89-9212,89-9213,89-9214,89-9215,89-9217, 88-6000, 88-6001, 88-6002, 88-6003, 88-6004, 88-6005, 88-6006
--	--



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Deep Well Plates
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Deep Well Plates	02-1016,02-1116,02-1216,02-1316,02-1022,02-1122,02-1222,02-1322,02-2010-50,02-2110,02-2210,02-2310,02-6022,02-6122,02-6222,02-6322,02-7022,02-7122,02-7222,02-7322,02-8005,02-8105,02-8205,02-8305,02-9010,02-9110,02-9210,02-9310,02-0096,02-0196,02-0008,02-1096,02-1196,02-2096,02-2196,02-2296,02-3024



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Pipet Tips
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

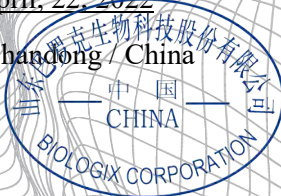
We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April, 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Pipet Tips	20-0010,21-0010,20-0200,21-0200,20-1000,21-1000,20-1250,21-1250,20-1251, 22-0010, 22-0011, 22-0200, 22-0201, 22-1000, 22-1001,23-0010,23-0011, 23-1010,23-0100,23-0200,23-0201,23-1000,23-1001,22-0100S, 22-0200S, 22-0201S,23-0010S,23-0011S,23-0021S,23-0051S,23-0101S,23-0200S,23-0201S,23-1001S,23-0010A, 23-0020A,23-0100A,23-0200A,23-0200A1,23-0200A2, 23-1000A,23-1001A,23-0010B,23-0200B,23-0011B, 23-0201B,23-0010H,23-0200H,23-1000H,23-1250H, 23-0011H,23-0201H,23-1251H,23-0010E,23-0200E, 23-1000E,23-0020ER,23-0100ER,23-0200ER,AB23-0020,AB23-0020S,AB23-0021,AB23-0021S,AB23-0050,AB23-0050S,AB23-0051,AB23-0051S,AB23-0250,AB23-0250S,AB23-0251,AB23-0251S,AT23-0020C,AT23-0020CS,AT23-0021C,AT23-0021CS,AT23-0020,AT23-0020S,AT23-0021,AT23-0021S,AT23-0050C,AT23-0050CS,AT23-0051C,AT23-0051CS,AT23-0050,AT23-0050S,AT23-0051,AT23-0051S,AT23-0200C,AT23-0200CS,AT23-0201C,AT23-0201CS, AT23-0200,AT23-0200S,AT23-0201,AT23-0201S, AT23-1000C,AT23-1000CS,AT23-1001C,AT23-1001CS,AT23-1000,AT23-1000S,AT23-1001,AT23-1001S,AT21-0050M,AT21-0050MS,AT23-0050M,AT23-0050MS,AT23-0051M,AT23-0051MS,AT21-0200M,AT21-0200MS,AT23-0201M, AT23-0201MS,AH23-0050C,AH23-0050CS,AH23-0051C,AH23-0051CS,AH23-0050,AH23-0050S,AH23-0051,AH23-0051S,AH23-0300C,AH23-0300CS,AH23-0301C,AH23-0301CS,AH23-0300,AH23-0300S,AH23-0301,AH23-0301S,AH23-1000C,AH23-1000CS,AH23-1001C,AH23-1001CS,AH23-1000,AH23-1000S,AH23-1001,AH23-1001S,AA21-0030S,AA23-0250S,AA23-0250S,AA23-0251,AA23-0251S, R21-0020, R21-0021, R23-0020, R23-0021, R21-0200, R21-0201, R23-0200,R23-0201, R21-1000, R21-1001, R23-1000, R23-1001, AA23-0030, AA23-0030S, AA23-0031, AA23-0031S, AA23-0250, AA23-0250S, AA23-0251, AA23-0251S, AZ23-0050, AZ23-0050S, AZ23-0051, AZ23-0051S, AZ23-0200, AZ23-0200S, AZ23-0201, AZ23-0201S



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Reagent Bottles
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April, 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Reagent Bottles	04-0060,04-0125,04-0200,04-0500,04-1250,04-0008U,04-0015U,04-0030U,04-0060U,04-0125U,04-0250U,04-0500U,04-0100U,04-1008U,04-1015U,04-1030U,04-1060U,04-1125U,04-1250U,04-1500U,04-1100U,04-2008,04-2015,04-2030,04-2060,04-2100,04-2125,04-2250,04-2500,04-3008,04-3015,04-3030,04-3060,04-3100,04-3125,04-3250,04-3500,04-0008US,04-0015US,04-0030US,04-0060US,04-0125US,04-0250US,04-0500US,04-0100US,04-1008US,04-1015US,04-1030US,04-1060US,04-1125US,04-1250US,04-1500US,04-1100US,04-2008S,04-2015S,04-2030S,04-2060S,04-2125S,04-2250S,04-2500S,04-2100S,04-3008S,04-3015S,04-3030S,04-3060S,04-3125S,04-3250S,04-3500S,04-3100S



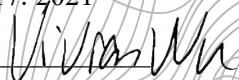
DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Sealing Films
Models: See Annex
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 

Position: Director

Date: April 22, 2022

Place: Shandong / China



Annex

Product Name	Model
Sealing Films	61-0010,61-0110,61-0013,61-0012,61-0015,61-0014,61-0011,61-0120,61-0121,61-0125,61-0030,61-0031,61-0040,61-0041,61-0210,61-0250,61-0020,61-0025,61-0080,61-0081,61-0145,61-0050,61-0051,61-0152,61-0153,61-0060,61-0061,61-0070,61-0071,61-0072,61-0301,61-0302,61-0303,61-0304,61-0130,61-0131,61-0132,61-0401,61-0411



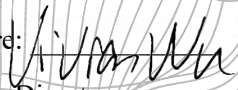
DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Solution Basins
Specification: 25-0051,25-0052,25-1025,25-1100,25-1202
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April, 22, 2022

Place: Shandong / China





DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Biologix Corporation
Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,
Jinan, 250101 Shandong, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Transfer Pipets
Specification: 30-0135,30-0135A1,30-0138,30-0138A1,30-0238A1
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN 15223-1: 2021
EN ISO 20417: 2021

Signature: 
Position: Director

Date: April, 22, 2022

Place: Shandong / China

