



# 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  
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-