



# DECLARATION OF CONFORMITY

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

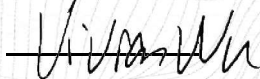
**Manufacturer:** Biologix Corporation  
**Address:** No.2766 Ying Xiu Road, High-Tech Industrial Development Zone,  
Jinan, 250101 Shandong, China

**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.

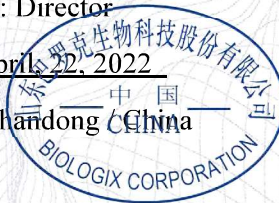
EN ISO 14971:2019      EN ISO 18113-1:2011      EN 15223-1: 2021  
EN ISO 20417: 2021

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