



# 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:** Inoculating Loops & Needles  
**Specification:** 65-0001,65-0002,65-0010  
**Classification:** Others (IVDD)  
**Conformity Assessment Procedure:** Annex III of In Vitro Diagnostic Directive (98/79/EC)

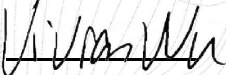
We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

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

