



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: Strainers
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
Strainers	15-1040,15-1070,15-1100,08-PES1322R,08-PES2522R,08-PES3022R,08-PES3322S,08-PES3345S,08-PES3322M,08-PES3345M,08-CA3022R,08-CA3045R,09-PES2250,09-PES2250F,09-CA2250,09-CA2250F,09-PES2210,09-PES4510, 09-PES4550