



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

Manufacturer:

Name: Biologix Corporation

Address: No.2766 Ying Xiu Road, High-Tech Industrial Development Zone Jinan, Shandong, China

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Virus Collection Tube & Transportation, Preservation Medium

Model: 19-1301 19-1302 19-1252 19-1251 19-1262 19-1261 19-1121 19-1122

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 14971:2012

EN 15223-1:2016

EN ISO18113-1:2011

EN ISO18113-3:2011

On behalf of SUNGO Europe office, I confirm we are EU REP of the company who issue this document.

Signature:

A handwritten signature in blue ink is written over a circular red stamp. Below the signature, the date '2020-4-26' is handwritten in blue ink. The red stamp contains some illegible text and numbers.

Date:



A handwritten signature in blue ink, written over a horizontal blue line.

Authorized Signature (S)