CE

DECLARATION OF CONFORMITY

Regarding In 98/79/EC -Annex II and Annex III In Vitro Diagnostic Medical Device Directive

Manufacturer:

Company name: Suzhou Bioselec Biotechnology Co., Ltd.

Address: 10, Qunxing 3rd road, Suzhou Industrial Park, Jiangsu Province,China.

E-mail: wayne@bioyx.cn

Whose Authorized Representative:

Name:: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the **98/79/EC**.

Product Name	Pipette Tips, Automation Pipet Tips, Microplates, Centrifuge Tube, PCR Tube and Plate, Cell Culture Plate,Cell Culture Flask, Cell Culture Dish, Elisa Plate, Serological Pipette, Centrifuge Bottle, Erlenmeyer Flask, Deep Well Plate,Tip Comb,Syringe Filter cf-DNA/cf-RNA Preservative Tube, Cryogenic Vial, Cell Factory, Screw Cap tube, Sampling Tube Waste Bags, Sharp Containers, Biohazard Bag.
Conformity Assessment Route	Annex II and Annex III

Applicable Standards and CS:

ISO 20417:2021
EN ISO 18113-1:2011
ISO 14971:2019
EN 15223-1:2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of **98/79/EC**. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:Wayne Zhang

Name of authorized signatory:

Suzhou Bioselec Biotechnology Co., Ltd.

Date:APR.02.2022

Position held in the company: General Manager

Place:Suzhou , China

Suzhou Bioselec Biotechnology Co., Ltd.

Digitally signed by Cosnicean Mihai
Date: 2023.03.09 13:13:53 EET
Reason: MoldSign Signature
Location: Moldova