

Declaration of Conformity

Manufacturer: Taizhou Sun Trine Biotechnology Co., Ltd.

Address: No.420 Jianggao Avenue, Medical High-tech Zone, Taizhou City, Jiangsu Province, China

EU Authorised Representative:

Osmunda Medical Technology Service GmbH

Address: Von Oppen-Weg 15, 14476 Potsdam, Germany

DIMDI code: DE/0000047267

Product: Viral Transport Medium Tube with Swab

Classification (IVDD, Annex II): IVD Device other than the ones listed in Annex II-IVDD 98/79 as List A, List B and Self testing

Conformity assessment route: ANNEX III

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directives and Standards (IVDD 98/79/EC). All supporting documentations are retained under the premises of the manufacturer.



General applicable directives:

In Vitro Diagnostic Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 (IVDD 98/79/EC).

Standard Applied:

EN ISO 13485:2016

EN ISO 14971:2012

EN ISO 23640: 2015

EN ISO 18113-1:2011

EN ISO 18113-2:2011

BS EN ISO 15223-1:2016

EN 13612:2002

EN ISO 11137-1:2015

Place, Date of Issue:

Taizhou, 15 April 2020

Represented by General manager:

Name: YangXie

Function: General Manager

Signature:



The signature is signed on behalf of Taizhou Sun Trine Biotechnology Co., Ltd.