SALUBRIS, Inc. GATEWAY TO HEALTH, WORLDWIDE

CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC Of the European Parliament and of the Council of 27th October 1998 on In Vitro Medical Diagnostic Devices

Salubris, Inc. hereby declares under its own responsibility that the product covered by the declaration is conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

Manufacturer:	SALUBRIS, Inc. One Boston Place, Suite 2600 Boston, MA 02108, U.S.A. Tel: (800) 326-1484, Fax: (617) 249-0803, website: www.salubrisinc.com, e-mail: info@salubrisinc.com
Authorised representative:	SALUBRIS, 2, Clos de Toussue 27300 Menneval - FRANCE Tel: +33 683 00 84 77,
Product Name:	NUCLISWAB®
Product Code:	TS060
Description:	NUCLISWAB® is a transport system used for collection and transport of cells and viruses from clinical samples or from environment, for isolation of nucleic acids that will be used in nucleic acid amplification tests.
Classification:	Article 9, paragraph 1 of EC Council Directive 98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route:	According to Annex III of the IVD Directive 98/79/EC
Applied Standards:	The following regulations and standards have been applied:

- **EN ISO 9001:2015** - Quality Management Systems-Requirements
- **EN ISO 13485:2016** - Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN ISO 14971:2019** - Medical devices - Application of risk management to medical devices
- **EN ISO 18113-1:2011** - In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
- **EN 13612:2002** - Performance evaluation of in vitro diagnostic medical devices

April 1st, 2020
Thomas SILIER, M.D.
President