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EU - DECLARATION OF CONFORMITY
IVDR 2017/746
MSwab®

MANUFACTURER:	*Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*MSwab®* *(See the attached list of product code)*
INTENDED PURPOSE:	*The MSwab® system is used for the collection, transport and preservation of clinical specimens containing Gram positive aerobic and facultative anaerobic bacteria, HSV 1 and HSV 2 from the collection site to the testing laboratory. In the laboratory, MSwab® specimens are processed using standard clinical laboratory operating procedures for culture.*
BASIC UDI-DI:	*80533260BD0360AM0049Y*
CLASSIFICATION ACCORDING TO IVDR 2017/746 (ANNEX VIII):	Class A non-sterile, Rule 5
CONFORMITY ASSESSMENT ROUTE:	*Annex II + Annex III (Annex IV)*
NOTIFIED BODY:	*N.A.*
EU CERTIFICATE NUMBER AND VALIDITY:	*N.A.*

Under our own sole responsibility, we hereby declare that the products, as specified in the product list, meet the provisions of Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

This declaration is supported by the Quality System certification based on the standard **EN ISO 13485:2016 Quality Management System certificate.**

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PRODUCT-LIST
MSwab® kit

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
404C*	1,6 mL of MSwab® medium + regular FLOQSwabs®

**This kit contains the Medical Device FLOQSwabs® and/or CLASSIQSwabs™ manufactured by COPAN ITALIA S.p.A, located in via F. Perotti 10, 25125 Brescia, Italy. This product satisfies the Essential Requirements of the Directive 93/42/EEC dated 14th June 1993, concerning Medical Devices, Annex I and following updates, and it is covered by the "EC-certificate- Full Quality Assurance System- Annex II of MDD 93/42/EEC" No. G1 073936 0014 REV.03 issued on by the Notified Body (Identification N.0123) TÜV SÜD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München – Germany.*

Place, Date of First Issue: Brescia, 18/05/2022
Place, Current Version Issued on: Brescia, 31/01/2023

Elisabetta Zanella
Chief Regulatory Officer
COPAN ITALIA S.p.A