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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 from the collection site to the testing laboratory. In the laboratory, specimens collected in MSwab® system can be analysed using standard clinical procedures for:* • *bacterial culture of aerobic and facultative anaerobic gram-positive microorganisms;* • *viral colture of HSV 1 and HSV 2 viruses;* • *Nucleic acid detection of bacteria and viruses.*
BASIC UDI-DI:	*80533260CD0350AM004AE*
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® in bulk

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
6E011N	1 mL preservation medium
6E076N	3 mL preservation medium
6U019N	2 mL preservation medium

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