EU - DECLARATION OF CONFORMITY
IVDR 2017/746
SL Solution™

MANUFACTURER:	*Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*SL Solution™* *(See the attached list of product code)*
INTENDED PURPOSE:	*Copan SL Solution™ is a treatment reagent for fluidification of specimens collected from the respiratory tract prior to subsequent microbiological analyses.*
BASIC UDI-DI:	*80533260ED0270AM004CT*
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
SL Solution™

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
0E005N	Sputum Liquefying Solution 1 mL Tube in bulk
0E006N.A	Sputum Liquefying Solution 1 mL Tube in bulk for automation
0U019N	SL SOLUTION 1ML IN BULK
0U020N.A	SL SOLUTION 1ML + TRANSFER DEVICE IN BULK
0E003N	Sputum Liquefying Solution 1 mL + Sterile Pasteur Pipette 3 mL
0E004N.A	Sputum Liquefying Solution 1 mL + Sterile Pasteur Pipette 3 mL for automation

Place, Date of First Issue: Brescia, 18/05/2022
Place, Current Version Issued on: Brescia, 24/03/2023

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