

**EC-DECLARATION OF CONFORMITY**  
**SL Solution™**  
**IN VITRO DIAGNOSTIC DEVICE**

**Manufacturer:** Copan Italia S.p.A.  
Via Perotti, 10  
25125 Brescia, Italy

**European Representative:** N.A.

**Product Identification:** SL Solution™  
(See the attached product-list)

**Classification**  
**(according to 98/79/EC):** General/other IVD

**Conformity assessment**  
**route:** Annex III (IVDD)

*Under our own sole responsibility, we herewith declare that the products as specified in the product-list meet the provisions of the Council Directive 98/79/EC for in vitro medical devices and following amendments. 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**

**Valid until:** 26<sup>th</sup> May 2027

**PRODUCT-LIST**

***SL Solution™***

<b>PRODUCT CODE</b>	<b>PRODUCT NAME</b>
<b>2U063S01</b>	SPUTUM DIPPER IN BULK FOR PREHENSILE CAP

**Place, Date of Issue:** Brescia, 25<sup>th</sup> May 2022

**Place, Date of Print:** Brescia, 17<sup>th</sup> November 2023



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