

**EC-DECLARATION OF CONFORMITY  
CALIBRATED PLASTICS LOOPS  
IN VITRO DIAGNOSTIC DEVICE**

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

**European Representative:** N.A.

**Product Identification:** Calibrated Plastic Loops  
(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**  
***Calibrated Plastic Loops***

<b>PRODUCT CODE</b>	<b>PRODUCT NAME</b>
<b>175CS01</b>	LOOPS 1UL HARD B/01PCS 500PKG
<b>175CSR40.J</b>	ANSE 1UL HARD RICH.4000PCS
<b>176CS01</b>	NEEDLES B/01PCS 500PKG
<b>176CS20</b>	NEEDLES B/20PCS 4000PKG
<b>176CSR40</b>	NEEDLES B/40PCS 4000PKG RICH.
<b>177CS01</b>	LOOPS 10UL HARD B/01PCS 500PKG
<b>178CS01</b>	LOOPS 1UL SOFT 500PKG
<b>178CS10</b>	ANSE PER INOC 1UL SOFT 2000PKG
<b>178CS20</b>	ANSE 1UL SOFT B/20PZ 4000PKG
<b>178CS40</b>	ANSE X INOCULAZIONE UL 1 SOFT
<b>178CS50</b>	LOOPS 1UL SOFT 50PCS PACKED
<b>178CSR40</b>	ANSE 1UL SOFT RICH. 4000PKG
<b>179CS01</b>	LOOPS 10UL SOFT B/01PCS 500PKG
<b>179CS10</b>	ANSE PER INOCULAZ.10 UL SOFT
<b>179CS20</b>	LOOPS 10UL SOFT B/20PZ 4000PKG
<b>179CSR40</b>	ANSE 10UL SOFT RICH. 4000PKG
<b>183CS10</b>	MINI NEEDLES 10PCS 2000PKG
<b>183CS20</b>	MINI NEEDLES 20PCS 4000PKG
<b>1U015S50</b>	LOOPS 10 UL SOFT 50PCS PACKED
<b>8175CS10H</b>	LOOPS 1UL HARD 2000 PKG
<b>SL1H</b>	INOC.LOOPS 1UL-HARD PKG 3200
<b>8175CS20H</b>	LOOPS 1UL HARD 4000PKG
<b>8175CSR40H</b>	ANSE 1UL HARD RICH.4000PCS
<b>SN20</b>	STERILE NEEDLES PKG. 4000 PCS

<b>8177CS10H</b>	LOOPS 10UL HARD 2000PKG
<b>SL10H</b>	INOC.LOOPS 10UL-HARD PKG.3200
<b>8177CS20H</b>	LOOPS 10UL HARD 4000PKG
<b>8177CS50H</b>	ANSE X INOCULAZIONE UL 10
<b>8177CSR40H</b>	ANSE 10UL HARD RICH. 4000PCS
<b>SL1S</b>	INOC.LOOPS 1UL-SOFT PKG.3200
<b>SL10S</b>	INOC.LOOPS 10UL-SOFT PKG.3200

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

**Place, Date of Print:** Brescia, 26<sup>th</sup> September 2023



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