

**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: 26th May 2027

PRODUCT-LIST***Calibrated Plastic Loops***

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

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

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Chief Regulatory Officer
COPAN ITALIA S.p.A