COPAN
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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
178CS01	LOOPS 1UL SOFT 500PKG
178CS10	ANSE PER INOC 1UL SOFT 2000PKG
178CS20	ANSE 1UL SOFT B/20PZ 4000PKG
179CS01	LOOPS 10UL SOFT B/01PCS 500PKG
179CS10	ANSE PER INOCULAZ.10 UL SOFT
179CS20	LOOPS 10UL SOFT B/20PZ 4000PKG

Place, Date of Issue: Brescia, 25th May 2022

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