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EU - DECLARATION OF CONFORMITY MDR 2017/745

LolliSponge™

MANUFACTURER:	*Copan Italia* *Via Perotti, 10 – 25125 Brescia - Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*LolliSponge™* *(See the attached list of product code)*
INTENDED PURPOSE:	*Copan LolliSponge™ is a saliva specimen collection system.*
BASIC UDI-DI:	*80533260AD02401M00325*
CLASSIFICATION ACCORDING TO MDR 2017/745 (ANNEX VIII):	*Class I no 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 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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

LolliSponge™

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
1E063N01	*Self LolliSponge™ Saliva Collection Device*
1E062N50	*Self LolliSponge™ Saliva Collection Device – bag of 50 pcs*

Place, Date of First Issue: Brescia, 26/05/2021
Place, Current Version Issued on: Brescia, 31/01/2023

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