COPAN
Innovating Together

EC-DECLARATION OF CONFORMITY
hDNA Free FLOQSwabs ®
MEDICAL DEVICE

Manufacturer:	*Copan Italia S.p.A.* *Via Perotti, 10* *25125 Brescia, Italia*
European Representative:	*N.A.*
Product family:	*FLOQSwabs®* *(See the attached product list)*
Classification (according to 93/42/EEC):	*Class IIa, Rule 6*
Conformity assessment route:	*Annex II, excluding Section 4 (MDD)*

Under our own sole responsibility, we herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for 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***

Notified Body:	*TÜV SÜD PRODUCT SERVICE GmbH,* *Ridlerstraße 65, 80339 München-Germany,* *Notified Body Identification Number 0123*
EC Certificate(s):	G1 073936 0014 Rev. 03
Valid until:	26th May 2024

PRODUCT LIST

hDNA Free FLOQSwabs ®

CODE	DESCRIPTION
50U002DS01	Regular Flocked swab, 20 mm breaking point, individually wrapped
2502CS01	Regular flocked swab with molded braking point, single wrapped
50U003DS	Regular flocked swab, 20mm Break Point, plus 2ml cuvette in peel pouch
50U004DS	Regular flocked swab, 20mm Breaking Point, in long dry tube
50U008DS01	Regular flocked swab single wrapped
50U009DS02	Regular flocked swab, 2 pcs packed
50U006DS02	Regular flocked swab, 20mm Breaking Point, 2 pcs in peel pouch
50U027DS03	FLOQSwabs® hDNA Free Regular Molded bp 20mm, Sterile, 3pcs Packed

To all base code here before listed any prefix or suffix indicate only a customization regarding the packaging lay-out.

Place, Date of Issue: Brescia, 25th May 2021

Place, Date of Print: Brescia, 12th October 2023

Elisabetta Zanella
Chief Regulatory Officer