

EC-DECLARATION OF CONFORMITY
FecalSwab
IN VITRO DIAGNOSTIC DEVICE

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

European Representative: N.A.

Product Identification: FecalSwab
(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

FecalSwab

PRODUCT CODE	PRODUCT NAME
4U031S	2mL modified Cary Blair in bulk plus stool transfer device in bulk

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

Place, Date of Print: Brescia, 24th March 2023



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