

EC-DECLARATION OF CONFORMITY
eSwab®
MEDICAL DEVICE

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

European Representative: N.A.

Product family: eSwab®
(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**eSwab®**

CODE	DESCRIPTION
480CE/480C	ESWAB LQ AMIES REG. NYLON FLOCKED
480CESR/480CSR	ESWAB LQ AMIES REG. FLOCK DOUBLE WRAPPED
481CE/481C	ESWAB LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
482CE/482C	ESWAB LQ AMIES PERNASAL NYLON FLOCKED APPLICATOR
483CE	ESWAB LQ AMIES URETHRAL NYLON FLOCKED APPLICATOR
484CE	ESWAB LQ AMIES PEDIATRIC NYLON FLOCKED APPLICATOR
486C	ESWAB LQ AMIES REG. FLOCKED + RAYON PL. APPLICATOR
490CE.A	ESWAB AUTOM. LQ AMIES REG. NYLON FLOCKED APPLICATOR
490CESR.A	ESWAB LQ AMIES REG. FLOCK DOUBLE WRAPPED
490CE02	ESWAB LQ AMIES + 2 REGULAR APPLICATOR
491CE.A	ESWAB AUTOM. LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
492CE03	ESWAB LQ AMIES WITH 3 APPL:1 REGULAR+1 URETHRAL+1 NASOPHARINGEAL
493CE02	MRSA ESWAB 1 LQ AMIES TEST TUBE+1 PINK APPLICATOR+1 WHITE APPLICATOR
493CE03	MRSA ESWAB 1 LQ AMIES TEST TUBE+2 PINK APPLICATORS+1 WHITE APPLICATOR
4E011S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES REGULAR NYLON FLOCKED APPLICATOR
4E014S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
4C012S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES REGULAR NYLON FLOCKED APPLICATOR
480CE.IV	ESWAB LQ AMIES REG. NYLON FLOCKED APPLICATOR
480CFX	ESWAB PINK CAP LQ AMIES REG. NYLON FLOCKED APPLICATOR
493C02	1 LQ AMIES TEST TUBE + 1 PINK APPLICATOR + 1 WHITE APPLICATOR
493C03	1 LQ AMIES TEST TUBE+2 PINK APPLICATORS+1 WHITE APPLICATOR
4E039S	ESWAB LQ AMIES BLUE CAP + REGUL. FLOQSWAB
4E047S02	MRSA ESWAB 1 LQ AMIES TUBE WHITE CAP + 1 PINK APPL. + 1 WHITE APPL.
4E030S	ESWAB LQ AMIES 2mL REG. NYLON FLOCKED APPLICATOR
4E033S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES FLEXIBLE NYLON FLOCKED APPLICATOR
4E053S.A	ESWAB 1ML WHITE CAP + REGULAR FLOQSWAB AUTOMATION
480CFA	ESWAB LQ AMIES, NON-CAPTURE PURPLE CAP, REG. NYLON FLOCKED APPLICATOR

4E051S.MLS	ESWAB AUTOM. LQ AMIES REG. NYLON FLOCKED APPLICATOR
4E074S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES FLEXIBLE NYLON FLOCKED SWAB
4E068S.A	ESWAB AUTOM. ROUND TUBE LQ AMIES MINI FLEXIBLE FLOCKED SWAB
4E076S	ESWAB LQ AMIES FLEXIBLE PROGRESSIVE FLOQSWABS
4E077S	ESWAB LQ AMIES MINI FLEXIBLE PROGRESSIVE FLOQSWABS
4C109S01	ESWAB LQ AMIES 2 mL REG. NYLON FLOCKED APPLICATOR
4E134S	ESWAB LQ AMIES URETHRAL FLOCKED APPLICATOR
4E135S	ESwab® Pink cap, Round tube LQ Amies Regular Nylon Flocked Applicator

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