

**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 “eSwab®”)*

**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 SUD PRODUCT SERVICE GmbH,  
Ridlerstraße 65, 80339 München-Germany,  
Notified Body Identification Number 0123*

**EC Certificate(s):** *G1 073936 0014 Rev. 03*

**Valid until:** *26<sup>th</sup> May 2024*

**PRODUCT LIST****eSwab®**

<b>Product Code</b>	<b>Description</b>
<b>480CE/480C</b>	ESWAB LQ AMIES REG. NYLON FLOCKED
<b>480CESR/480CSR</b>	ESWAB LQ AMIES REG. FLOCK DOUBLE WRAPPED
<b>481CE/481C</b>	ESWAB LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
<b>482CE/482C</b>	ESWAB LQ AMIES PERNASAL NYLON FLOCKED APPLICATOR
<b>483CE</b>	ESWAB LQ AMIES URETHRAL NYLON FLOCKED APPLICATOR
<b>484CE</b>	ESWAB LQ AMIES PEDIATRIC NYLON FLOCKED APPLICATOR
<b>486C</b>	ESWAB LQ AMIES REG. FLOCKED + RAYON PL. APPLICATOR
<b>490CE.A</b>	ESWAB AUTOM. LQ AMIES REG. NYLON FLOCKED APPLICATOR
<b>490CESR.A</b>	ESWAB LQ AMIES REG. FLOCK DOUBLE WRAPPED
<b>490CE02</b>	ESWAB LQ AMIES + 2 REGULAR APPLICATOR
<b>490CE02.A</b>	ESWAB AUTOM. LQ AMIES + 2 REGULAR APPLICATOR
<b>491CE.A</b>	ESWAB AUTOM. LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
<b>492CE03</b>	ESWAB LQ AMIES WITH 3 APPL:1 REGULAR+1 URETHRAL+1 NASOPHARINGEAL
<b>493CE02</b>	MRSA ESWAB 1 LQ AMIES TEST TUBE+1 PINK APPLICATOR+1 WHITE APPLICATOR
<b>493CE03</b>	MRSA ESWAB 1 LQ AMIES TEST TUBE+2 PINK APPLICATORS+1 WHITE APPLICATOR
<b>4E011S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES REGULAR NYLON FLOCKED APPLICATOR
<b>4E014S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES MINITIP NYLON FLOCKED APPLICATOR
<b>4C012S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES REGULAR NYLON FLOCKED APPLICATOR
<b>480CE.IV</b>	ESWAB LQ AMIES REG. NYLON FLOCKED APPLICATOR
<b>480CFX</b>	ESWAB PINK CAP LQ AMIES REG. NYLON FLOCKED APPLICATOR
<b>480CSP</b>	ESWAB LIQUID AMIES PEEL POUCH W/O PRECUT REGULAR FLOCKED APPLICATOR
<b>493C02</b>	1 LQ AMIES TEST TUBE + 1 PINK APPLICATOR + 1 WHITE APPLICATOR
<b>493C03</b>	1 LQ AMIES TEST TUBE+2 PINK APPLICATORS+1 WHITE APPLICATOR
<b>4E039S</b>	ESWAB LQ AMIES BLUE CAP + REGUL. FLOQSWAB
<b>4E047S02</b>	MRSA ESWAB 1 LQ AMIES TUBE WHITE CAP + 1 PINK APPL. + 1 WHITE APPL.
<b>4E030S</b>	ESWAB LQ AMIES 2mL REG. NYLON FLOCKED APPLICATOR
<b>4E033S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES FLEXIBLE NYLON FLOCKED APPLICATOR
<b>4E053S.A</b>	ESWAB 1ML WHITE CAP + REGULAR FLOQSWAB AUTOMATION
<b>480CFA</b>	ESWAB LQ AMIES, NON CAPTURE PURPLE CAP, REG. NYLON FLOCKED APPLICATOR
<b>4E051S.MLS</b>	ESWAB AUTOM. LQ AMIES REG. NYLON FLOCKED APPLICATOR
<b>481CE.NOR</b>	ESWAB LQ AMIES MINITIP NYLON FLOCKED APPLICATOR

<b>4E074S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES FLEXIBLE NYLON FLOCKED SWAB
<b>4E068S.A</b>	ESWAB AUTOM. ROUND TUBE LQ AMIES MINI FLEXIBLE FLOCKED SWAB
<b>4E076S</b>	ESWAB LQ AMIES FLEXIBLE PROGRESSIVE FLOQSWABS
<b>4E077S</b>	ESWAB LQ AMIES MINI FLEXIBLE PROGRESSIVE FLOQSWABS
<b>4C109S01</b>	ESWAB LQ AMIES 2 mL REG. 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, 24<sup>th</sup> July 2020



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Elisabetta Zanella  
Chief Regulatory Officer