

EC-DECLARATION OF CONFORMITY
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 "FLOQSwabs®")*

**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: *26th May 2024*

PRODUCT LIST**FLOQSwabs®**

Product Code	Description
503CS01.SX	FLOQSwabs® flexible sterile single wrapped, molded bp 100mm
519CS01.SX	FLOQSwabs® regular, sterile single wrapped, molded bp 100mm
5E086S01.TA	Regular thick, sterile, single wrapped
5U085S	Regular thick, sterile, in tube
552C.ROSE	Regular sterile in dry tube Molded Break Point 80 mm
5U002S	Regular FLOQSwabs®, sterile, in tube, 80mm breakpoint, with low stopper
5U032S	Regular FLOQSwabs®, no break point, sterile in tube
5U041S	Regular conic FLOQSwabs®, no break point, sterile, in dry tube
501CS01.Q20	Minitip FLOQSwabs® Sterile ind. wrapped, bp 60mm, bundles of 20
501CS01.Q25	Minitip FLOQSwabs®, Sterile Single Wrapped, bp 60mm, bundles of 25 pcs
502CS01.20	Regular FLOQSwabs®, Sterile Single Wrapped, bp 80mm bundles of 20
511CS01	Cone shaped FLOQSwabs®, Sterile Single Wrapped
516C	Mini Flexible FLOQSwabs®, sterile in dry tube, molded bp 100 mm
517CS01	FLOQSwabs® urethral/Endocervical, sterile single wrapped
518C	Minitip FLOQSwabs® Sterile, Molded break point 100 mm
519C	Regular FLOQSwabs® Sterile, Molded break point 100 mm
519CS01.20	Regular FLOQSwabs®, Sterile Single Wrapped, bp 100mm bundles of 20
520C	Regular FLOQSwabs®, Sterile in dry tube, Molded break point 30 mm
528C	Large Tip FLOQSwabs®, handle with stopper, in dry tube
52980C	Cone shaped FLOQSwabs® in tube, sterile Molded Break Point 80 mm
534C	Flexible Nylon FLOQSwabs®, Sterile in dry tube
535C	Mini Flexible Nylon FLOQSwabs®, sterile in dry tube
551C	Minitip FLOQSwabs® Sterile in dry tube, Molded Break Point 80 mm
552C	Regular FLOQSwabs® sterile in dry tube Molded Break Point 80 mm
552CV	Regular FLOQSwabs® sterile in dry tube, Green Cap break point 80 mm
553C	Flexible FLOQSwabs® Sterile in dry tube, molded bp 100 mm
560C	Ultra-Thin Minitip FLOQSwabs® Sterile in dry tube, molded bp 80mm
56780CS01	Contoured FLOQSwabs® with low stopper, sterile single wrapped, molded bp 80 mm
570CS01	FLOQSwabs® L-Shape Endo/Esocervical, sterile single wrapped, molded bp 80mm
46560CS01	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 60mm
5U030S01	Regular FLOQSwabs®, BP100mm no mark, Sterile, 1pc/pouch
501CS01	Minitip FLOQSwabs®, Sterile Single Wrapped, Molded bp 80mm
501CS01.10	Minitip FLOQSwabs®, Sterile Single Wrapped, bp 80mm bundles of 10
502CS01	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 80mm
502CS01.US	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 80mm
503CS01	Flexible FLOQSwabs®, Sterile Single Wrapped, Molded bp 100mm
516CS01	Mini Flexible FLOQSwabs®, sterile single wrapped, molded bp 100 mm
516CS01.26	Mini Flexible FLOQSwabs®, sterile single wrapped, bp 100 mm, 26pcs packed
518CS01	Minitip FLOQSwabs®, Ster. Single Wrapped, Molded bp 100mm
519CS01	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp

520CS01	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 30mm
525CS01	Ultra-Thin minitip FLOQSwabs®, sterile single wrapped, molded bp 80 mm
53380CS01	Regular FLOQSwabs®, Sterile Single Wrapped, bp 80mm
534CS01	Flexible Nylon FLOQSwabs®, Sterile Single Wrapp
534100CS01	Flexible Nylon FLOQSwabs®, Sterile Single Wrapped, Molded bp 100mm
535CS01	Mini Flexible Nylon FLOQSwabs®, sterile single wrapped
536CS01	Regular FLOQSwabs®, unbreakable, sterile single wrapped
537CS01	Nylon Regular FLOQSwabs®, unbreakable, sterile single wrapped
56380CS01	Long contoured FLOQSwabs® with stopper, sterile single wrapped, molded bp 80 mm
56750CS01	Short contoured FLOQSwabs® with stopper, sterile single wrapped, molded bp 50 mm
5U005S	Dual conic FLOQSwabs®, w/o breakpoint, in pouch
5U051S	Regular plus FLOQSwabs®, rounded tip, sterile, in dry tube
5U058S	Regular plus FLOQSwabs®, rounded tip, sterile, in dry tube
5E007S01	FLOQBrush™ soft velvet-like slim tip brush, sterile, single wrapped, molded BP 80 mm
5C066S01	Soft velvet-like slim tip FLOQSwabs®, sterile, single wrapped, molded BP 80 mm
5U065S01	Regular FLOQSwabs®, Sterile, single wrapped, molded BP 21 mm covered by flocked area
5U061S02	Regular FLOQSwabs®, Sterile, 2pcs packed, molded BP 21mm covered by flocked area
5U067S	Regular FLOQSwabs®, Sterile in dry tube, molded BP 21 mm covered by flocked area
5U069S01.20	Flexible minitip FLOQSwabs®, sterile single wrapped, bundles of 20
5U068S01.25	Flexible minitip FLOQSwabs®, sterile single wrapped, bundles of 25
5U044S01.TA	Pernasal flexible floqswab, sterile single wrapped
511CS01.PS	FLOQSwabs®, cone shaped, sterile single wrapped
553C.LC	Flexible FLOQSwabs® Sterile in dry tube, molded bp 100 mm
525CS01.Q	Ultra-Thin minitip FLOQSwabs®, sterile single wrapped, molded bp 80 mm
5U023S01.JP	FLOQSwabs® pernasal flexible, unbreakable, sterile single wrapped
5U024S01.JP	FLOQSwabs® regular, sterile single wrapped
5U053S01	Fine tip, BP 73 mm, sterile, in peel pouch
5U060S01	FLOQSwab® Nylon Regular Thick, sterile, single wrapped
5U073S01	Flexible FLOQSwab® single wrapped in bulk
5U074S01	Flexible minitip, sterile single wrapped, Bp 100mm, in bulk
5U084S01.26	Regular FLOQSwabs® Sterile Single Wrapped, bp 100mm, 26pcs packed
535CS01.AM	FLOQSwabs® neonatal, unbreakable, sterile single wrapped with separators
5E094S01.JP	FLOQSwabs® Regular thick, sterile, single wrapped
5U088S01	Progressive minitip FLOQSwab® wrapped, Bp80
519CS01.VER	FLOQSwabs® Regular, Sterile Single Wrapped, Molded bp
5U116S01	FLOQSwabs® Regular, Sterile Single Wrapped, Molded bp 20mm
5U098S02	FLOQSwabs® Regular, Sterile 2 pieces packed, molded bp 80mm
5E150S01	FLOQSwabs® Minitip, Sterile single wrapped, Molded bp 80mm

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, 28th January 2022



Elisabetta Zanella
Chief Regulatory Officer