

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

**PRODUCT LIST****FLOQSwabs®**

<b>Product Code</b>	<b>Description</b>
<b>46560CS01.CA</b>	FLOQSwabs® regular, sterile single wrapped, molded bp 60mm
<b>501CS01.CA</b>	FLOQSwabs® minitip, sterile single wrapped, molded bp 80mm
<b>502CS01.CA</b>	FLOQSwabs® regular, sterile single wrapped, molded bp 80mm
<b>503CS01.CA</b>	FLOQSwabs® flexible, sterile single wrapped, molded bp 100mm
<b>511CS01.CA</b>	FLOQSwabs® cone shaped, sterile single wrapped
<b>516C.CA</b>	FLOQSwabs® neonatal sterile in dry tube, molded bp 100mm
<b>516CS01.CA</b>	FLOQSwabs® neonatal, sterile single wrapped, molded bp 100mm
<b>518C.CA</b>	FLOQSwabs® minitip sterile, molded bp 100mm
<b>519C.CA</b>	FLOQSwabs® regular sterile, molded bp 100mm
<b>519CS01.CA</b>	FLOQSwabs® regular, sterile single wrapped, molded bp
<b>520C.CA</b>	FLOQSwabs® regular, sterile in dry tube, molded bp 30mm
<b>520CS01.CA</b>	FLOQSwabs® regular, sterile single wrapped, molded bp 30mm
<b>525CS01.CA</b>	FLOQSwabs® ultrathin\urethral, sterile single wrapped, molded bp 80mm
<b>528C.CA</b>	FLOQSwabs® large tip swab, hndle with stopper, in dry tube
<b>528CS01.CA</b>	FLOQSwabs® large tip swab, handle with stopper in pouch
<b>52980C.CA</b>	FLOQSwabs® cone shaped in tube, sterile molded bp 80mm
<b>551C.CA</b>	FLOQSwabs® minitip sterile in dry tube, molded bp 80mm
<b>552C.CA</b>	FLOQSwabs® regular sterile in dry tube molded bp 80mm
<b>553C.CA</b>	FLOQSwabs® flexible sterile in dry tube, molded bp 100mm
<b>560C.CA</b>	FLOQSwabs® ultrathin\urethral, sterile in dry tube, molded bp 80mm
<b>56380CS01.CA</b>	FLOQSwabs® midturbinate adult, sterile single wrapped, moled bp 80mm
<b>56750CS01.CA</b>	FLOQSwabs® midturbinate pediatric, sterile single wrapped, molded bp 50mm
<b>56780CS01.CA</b>	FLOQSwabs® midturbinate pediatric, sterile single wrapped, moled bp 80mm
<b>570CS01.CA</b>	FLOQSwabs® L-shape endo/esocervical, sterile single wrapped, molded bp 80mm
<b>5U002S.CA</b>	FLOQSwabs® regular, sterile, in tube, bp 80mm, with low stopper
<b>5U058S.CA</b>	FLOQSwabs® regular, sterile, single wrapped, molded bp 60mm
<b>503CS01.SX</b>	FLOQSwabs® flexible sterile single wrapped, molded bp 100mm
<b>519CS01.SX</b>	FLOQSwabs® regular, sterile single wrapped, molded bp 100mm
<b>5E086S01.TA</b>	Regular thick, sterile, single wrapped
<b>5U085S</b>	Regular thick, sterile, in tube
<b>552C.ROSE</b>	Regular sterile in dry tube Molded Break Point 80 mm
<b>5U002S</b>	Regular FLOQSwabs®, sterile, in tube, 80mm breakpoint, with low stopper
<b>5U032S</b>	Regular FLOQSwabs®, no break point, sterile in tube
<b>5U041S</b>	Regular conic FLOQSwabs®, no break point, sterile, in dry tube
<b>501CS01.Q20</b>	Minitip FLOQSwabs® Sterile ind. wrapped, bp 60mm, bundles of 20
<b>501CS01.Q25</b>	Minitip FLOQSwabs®, Sterile Single Wrapped, bp 60mm, bundles of 25 pcs
<b>502CS01.20</b>	Regular FLOQSwabs®, Sterile Single Wrapped, bp 80mm bundles of 20
<b>511CS01</b>	Cone shaped FLOQSwabs®, Sterile Single Wrapped
<b>516C</b>	Mini Flexible FLOQSwabs®, sterile in dry tube, molded bp 100 mm
<b>517CS01</b>	FLOQSwabs® urethral/Endocervical, sterile single wrapped

<b>518C</b>	Minitip FLOQSwabs® Sterile, Molded break point 100 mm
<b>519C</b>	Regular FLOQSwabs® Sterile, Molded break point 100 mm
<b>519CS01.20</b>	Regular FLOQSwabs®, Sterile Single Wrapped, bp 100mm bundles of 20
<b>520C</b>	Regular FLOQSwabs®, Sterile in dry tube, Molded break point 30 mm
<b>528C</b>	Large Tip FLOQSwabs®, handle with stopper, in dry tube
<b>52980C</b>	Cone shaped FLOQSwabs® in tube,sterile Molded Break Point 80 mm
<b>534C</b>	Flexible Nylon FLOQSwabs®, Sterile in dry tube
<b>535C</b>	Mini Flexible Nylon FLOQSwabs®, sterile in dry tube
<b>551C</b>	Minitip FLOQSwabs® Sterile in dry tube, Molded Break Point 80 mm
<b>552C</b>	Regular FLOQSwabs® sterile in dry tube Molded Break Point 80 mm
<b>552CV</b>	Regular FLOQSwabs® sterile in dry tube, Green Cap break point 80 mm
<b>553C</b>	Flexible FLOQSwabs® Sterile in dry tube, molded bp 100 mm
<b>560C</b>	Ultra-Thin Minitip FLOQSwabs® Sterile in dry tube, molded bp 80mm
<b>56780CS01</b>	Contoured FLOQSwabs® with low stopper, sterile single wrapped, molded bp 80 mm
<b>570CS01</b>	FLOQSwabs® L-Shape Endo/Esocervical, sterile single wrapped, molded bp 80mm
<b>46560CS01</b>	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 60mm
<b>5U030S01</b>	Regular FLOQSwabs®, BP100mm no mark, Sterile,1pc/pouch
<b>501CS01</b>	Minitip FLOQSwabs®, Sterile Single Wrapped, Molded bp 80mm
<b>501CS01.10</b>	Minitip FLOQSwabs®, Sterile Single Wrapped, bp 80mm bundles of 10
<b>502CS01</b>	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 80mm
<b>503CS01</b>	Flexible FLOQSwabs®, Sterile Single Wrapped, Molded bp 100mm
<b>516CS01</b>	Mini Flexible FLOQSwabs®, sterile single wrapped, molded bp 100 mm
<b>516CS01.26</b>	Mini Flexible FLOQSwabs®, sterile single wrapped, bp 100 mm, 26pcs packed
<b>518CS01</b>	Minitip FLOQSwabs®, Ster. Single Wrapped, Molded bp 100mm
<b>519CS01</b>	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp
<b>520CS01</b>	Regular FLOQSwabs®, Sterile Single Wrapped, Molded bp 30mm
<b>525CS01</b>	Ultra-Thin minitip FLOQSwabs®, sterile single wrapped, molded bp 80 mm
<b>53380CS01</b>	Regular FLOQSwabs®, Sterile Single Wrapped, bp 80mm
<b>534CS01</b>	Flexible Nylon FLOQSwabs®, Sterile Single Wrappes
<b>534100CS01</b>	Flexible Nylon FLOQSwabs®, Sterile Single Wrapped, Molded bp 100mm
<b>535CS01</b>	Mini Flexible Nylon FLOQSwabs®, sterile single wrapped
<b>536CS01</b>	Regular FLOQSwabs®, unbreakable, sterile single wrapped
<b>537CS01</b>	Nylon Regular FLOQSwabs®, unbreakable, sterile single wrapped
<b>56380CS01</b>	Long contoured FLOQSwabs® with stopper, sterile single wrapped, molded bp 80 mm
<b>56750CS01</b>	Short contoured FLOQSwabs® with stopper, sterile single wrapped, molded bp 50 mm
<b>5U005S</b>	Dual conic FLOQSwabs®, w/o breakpoint, in pouch
<b>5U051S</b>	Regular plus FLOQSwabs®, rounded tip, sterile, in dry tube
<b>5U058S</b>	Regular plus FLOQSwabs®, rounded tip, sterile, in dry tube
<b>5E007S01</b>	FLOQBrush™ soft velvet-like slim tip brush, sterile, single wrapped, molded BP 80 mm
<b>5C066S01</b>	Soft velvet-like slim tip FLOQSwabs®, sterile, single wrapped, molded BP 80 mm
<b>5U065S01</b>	Regular FLOQSwabs®, Sterile, single wrapped, molded BP 21 mm covered by flocked area
<b>5U061S02</b>	Regular FLOQSwabs®, Sterile, 2pcs packed, molded BP 21mm covered by flocked area
<b>5U067S</b>	Regular FLOQSwabs®, Sterile in dry tube, molded BP 21 mm covered by flocked area
<b>5U069S01.20</b>	Flexible minitip FLOQSwabs®, sterile single wrapped, bundles of 20

<b>5U068S01.25</b>	Flexible minitip FLOQSwabs®, sterile single wrapped, bundles of 25
<b>5U044S01.TA</b>	Pernasal flexible floqswab, sterile single wrapped
<b>511CS01.PS</b>	FLOQSwabs®, cone shaped, sterile single wrapped
<b>553C.CB</b>	Flexible FLOQSwabs® Sterile in dry tube, molded bp 100 mm
<b>553C.LC</b>	Flexible FLOQSwabs® Sterile in dry tube, molded bp 100 mm
<b>525CS01.Q</b>	Ultra-Thin minitip FLOQSwabs®, sterile single wrapped, molded bp 80 mm
<b>5U023S01.JP</b>	FLOQSwabs® pernasal flexible, unbreakable, sterile single wrapped
<b>5U024S01.JP</b>	FLOQSwabs® regular, sterile single wrapped
<b>5U053S01</b>	Fine tip, BP 73 mm, sterile, in peel pouch
<b>5U060S01</b>	FLOQSwab® Nylon Regular Thick, sterile, single wrapped
<b>5U073S01</b>	Flexible FLOQSwab® single wrapped in bulk
<b>5U074S01</b>	Flexible minitip, sterile single wrapped, Bp 100mm, in bulk
<b>5U084S01.26</b>	Regular FLOQSwabs® Sterile Single Wrapped, bp 100mm, 26pcs packed
<b>535CS01.AM</b>	FLOQSwabs® neonatal, unbreakable, sterile single wrapped with separators
<b>5E094S01.JP</b>	FLOQSwabs® Regular thick, sterile, single wrapped
<b>5U088S01</b>	Progressive minitip FLOQSwab® wrapped, Bp80
<b>519CS01.VER</b>	FLOQSwabs® Regular, Sterile Single Wrapped, Molded bp

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, 29<sup>th</sup> June 2020

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Elisabetta Zanella  
Chief Regulatory Officer