

EC-DECLARATION OF CONFORMITY
FLOQSwabs®
MEDICAL DEVICE

Manufacturer: *Copan Flock Technologies srl*
Via Perotti, 16-18
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 standards **UNI EN ISO 9001:2008 Quality System certificate** and **EN ISO 13485:2012/AC:2012 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 15 07 73935 003*

Valid until: *01st September 2020*

PRODUCT LIST**FLOQSwabs®**

CODE	DESCRIPTION
5U001S01	Fine tip sterile in pouch
5U002S	Regular sterile flocked in tube with low stopper
5U032S	Regular flocked swab
5U040S	Regular swab in dry tube without breaking point
5U041S	Regular conical swab in dry tube without breaking point
501CS01.Q10	Minitip swab
501CS01.Q100	Minitip swab
501CS01.Q20	Minitip swab
501CS01.Q25	Minitip swab
501CS01.10	Minitip swab
501CS01.20	Minitip swab
502CS01	Regular swab
502CS01.20	Regular swab
511CS01	Endocervical flocked swab, nylon velvet tip, plastic applicator, sterile, individually wrapped
516C	Pediatric flocked swab, nylon tip, plastic applicator, sterile in dry tube
517CS01	Universal flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
518C	Minitip sterile swab
519C	Regular flocked swab, nylon tip, plastic applicator, sterile in dry tube
520C	Regular flocked swab, nylon tip, plastic applicator, sterile in dry tube
528C	Large tip swab, handle with stopper, in dry tube
528CS01	Large tip swab, handle with stopper, in pouch
52980C	Cone Shaped Flock Swab, nylon velvet tip, plastic applicator, sterile in dry tube
534C	Flexible nasopharyngeal flocked swab, nylon tip, polyamide applicator, sterile in dry tube
534100CS01	Flexible nasopharyngeal flocked swab, nylon tip, polyamide applicator, sterile in dry tube
535C	Pediatric flocked swab, nylon tip, polyamide applicator, sterile in dry tube
550C	Regular flocked swab, nylon 7 mm tip, plastic applicator, sterile in dry tube
551C	Minitip flocked swab, nylon tip, plastic applicator, sterile in dry tube

552C	Regular flocked swab, nylon tip, plastic applicator, sterile in dry tube
552CV	Regular flocked swab, nylon tip, plastic applicator, sterile in dry tube
553C	Flexible nasopharyngeal flocked swab, nylon tip, plastic applicator, sterile in dry tube
560C	Ultra-thin/urethral flocked swab, nylon tip, plastic applicator, sterile in dry tube
56780CS01	MIDTURBINATE pediatric sterile single wrapped
570CS01	Endocervical L-Shaped Anatomic flocked swab, nylon tip, plastic applicator, sterile
46560CS01	REGULAR sterile single wrapped flockswab
5U009S01.CN	FLEXIBLE flockswab
5U010S01.CN	FLEXIBLE flockswab
5U016S01.CN	URETHRAL flockswab
5U023S01.JP	PERNASAL flockswab
5U024S01.JP	REGULAR flockswab
5U030S01	REGULAR flockswab
501CS01	Minitip flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
501CS01.10	Minitip flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
501CS01.20	Minitip flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
502CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
502CS01.20	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
503CS01	Flexible nasopharyngeal flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
503CS01.20	Flexible nasopharyngeal flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
516CS01	Pediatric flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
516CS01.26	Pediatric flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
518CS01	Minitip sterile single wrapped
519CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
519CS01.20	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
520CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
525CS01	Ultra-thin/urethral flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
52620CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped, breaking point 20 mm
53380CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
534CS01	Flexible nasopharyngeal flocked swab, nylon tip, polyamide applicator, sterile, individually wrapped

534100CS01	Flexible nasopharyngeal flocked swab, nylon tip, polyamide applicator, sterile, individually wrapped BP at 100 mm
535CS01	Pediatric flocked swab, nylon tip, polyamide applicator, sterile, individually wrapped
536CS01	Regular flocked swab, nylon tip, plastic applicator, sterile, individually wrapped, unbreakable stick
537CS01	Regular Thick flocked swab, nylon tip, plastic applicator, sterile, individually wrapped, unbreakable stick
56380CS01	MIDTURBINATE flocked swab, nylon tip, plastic applicator, sterile, individually wrapped
56750CS01	MIDTURBINATE Pediatric Flocked Swab, nylon tip, plastic applicator, sterile, individually wrapped, break point 50 mm
56780CS01	MIDTURBINATE Pediatric Flocked Swab, nylon tip, plastic applicator, sterile, individually wrapped
801CS01	Applicator for kit individually wrapped
5U005S	Dual conic swab without breaking point in pouch
552CS01	Regular in tube and pouch flocked swab with breaking point
5U051S	Rounded tip flocked swab, sterile in dry tube
5E046S	Vaginal self-sampling FLOQSwab in dry tube
5U058S	Regular Plus, rounded tip, sterile in dry tube,, with red mark
5U065S01	Regular, sterile, single wrapped, molded BP 21 mm covered by flocked area
5U061S02	Regular, sterile, 2 pcs packed, molded BP 21 mm covered by flocked area
5U067S	Regular, sterile in dry tube, molded BP 21 mm covered by flocked area
5E007S01	FLOQBrush™ soft velvet-like slim tip brush, sterile, single wrapped, molded BP 80 mm
5C066S01	Soft velvet-like slim tip brush, sterile, single wrapped, molded BP 80 mm

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 July 2017

Elisabetta Zanella
Chief Regulatory Officer