EU - DECLARATION OF CONFORMITY
IVDR 2017/746
UTM®

MANUFACTURER:	*Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*UTM®* *(See the attached list of product code)*
INTENDED PURPOSE:	*Copan Universal Transport Medium (UTM-RT®) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT® can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.*
BASIC UDI-DI:	*80533260BD0260AM0049D*
CLASSIFICATION ACCORDING TO IVDR 2017/746 (ANNEX VIII):	*Class A non-sterile, Rule 5*
CONFORMITY ASSESSMENT ROUTE:	*Annex II + Annex III (Annex IV)*
NOTIFIED BODY:	*N.A.*
EU CERTIFICATE NUMBER AND VALIDITY:	*N.A.*

Under our own sole responsibility, we hereby declare that the products, as specified in the product list, meet the provisions of Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. 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.**

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PRODUCT-LIST
UTM® kit

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
305C*	UTM 3 mL, Medium + Pernasal sterile Flocked Swab
306C*	UTM 3 mL, Medium + Regular sterile Flocked Swab
307C*	UTM KIT 3 mL, Medium + Minitip sterile Flocked Swab
321C*	UTM KIT 3 mL, Medium + Nasal Pharyngeal and Regular Flocked Swabs
323C*	UTM KIT 2 mL, Medium + Regular Flocked Swab
338C*	UTM KIT 3 mL, Medium+Minitip and Regular Flocked Swabs
346C*	UTM KIT 3 mL, Medium + Regular sterile Flocked Swab
347C*	UTM KIT 3 mL, Medium + Neonatal Minitip Flocked Swab
355C*	MINI UTM KIT 3 mL, Medium + Regular sterile Flocked Swab
355CW*	UTM MINI 3mL WHITE CAP+REGUL., Medium, white cap tube, regular flocked swab
357C*	MINI UTM KIT 3 mL, Medium + Urethral Flocked Swab
358C*	MINI UTM KIT 3 mL, Medium + Pernasal sterile Flocked Swab
359C*	MINI UTM KIT 1 mL, Medium + Regular sterile Flocked Swab
359CE.A*	MINI UTM KIT 1 mL – AUTOMATION, Medium + Regular Flocked Swab
360C*	MINI UTM KIT 1 mL, Medium + Pernasal sterile Flocked Swab
361C*	MINI UTM KIT 1 mL, Medium + Minitip sterile Flocked Swab
365C*	UTM KIT 2 mL, Medium + Pernasal Flocked Swab
366C*	UTM KIT 2 mL, Medium + Regular Flocked Swab
3C004N*	MINI UTM KIT 2 mL, medium in tube with capture cap + regular flocked
302C*	UTM KIT 3 mL, Medium + 2 Regular Polyester sterile Swabs
302C.LC*	UTM KIT 3 mL, Medium + 2 Regular Polyester sterile Swabs
328C*	UTM KIT 3 mL, Medium + Medium + Regular Polyester Swab

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
356C*	MINI UTM KIT 3 mL, Medium + Regular Polyester Swab
3C041N*	UTM KIT 3 mL, Medium + Long contoured with stopper Flocked Swab
3C042N*	MINI UTM KIT 3 mL, Medium + Minitip Flocked Swab
3U006N*	UTM KIT 3 mL, Medium in tube purple cap + pernasal FLOQSwabs®
3U008N*	UTM KIT 3 mL - NO BEADS, Medium in tube purple cap + pernasal FLOQSwabs®
3E076N05*	PodSwab™ - UTM KIT 6 mL, Medium + 5 Regular sterile Flocked swab BP30mm
305CMH*	UTM KIT 3 mL, Medium + Pernasal Flocked Swab
CA302MH*	UTM KIT 3 mL, Medium+Regular Flocked Swab
CA303MH*	UTM KIT 3 mL, Medium + Minitip Flocked Swab
3U053N*	MINI UTM KIT 2 mL

**This kit contains the Medical Device FLOQSwabs® and/or CLASSIQSwabs™ manufactured by COPAN ITALIA S.p.A, located in via F. Perotti 10, 25125 Brescia, Italy. This product satisfies the Essential Requirements of the Directive 93/42/EEC dated 14th June 1993, concerning Medical Devices, Annex I and following updates, and it is covered by the "EC-certificate- Full Quality Assurance System- Annex II of MDD 93/42/EEC" No. G1 073936 0014 REV.03 issued on by the Notified Body (Identification N.0123) TÜV SÜD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München – Germany.*

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Elisabetta Zanella
Chief Regulatory Officer
COPAN ITALIA S.p.A