



*DECLARATION OF CONFORMITY*  
*Medical Device TRANSYSTEM<sup>®</sup>, STERILE SWABS IN TUBE*

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificates", reference numbers : G1 10 07 73936 001 issued on September 02, 2010 valid until September 01, 2015 and delivered by TÜV SUD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München - Germany , Notified Body Identification Number 0123, and conform to the required technical documentation in accordance with Annex II of the " EC – Directives", the council Directive 93/42/ECC of 14 June 1993, and following updates, concerning medical devices (MDD)

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa (MDD), meet the provisions of the EC-Directives which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex II of the EC –Directive MDD.

The conformity of the production quality assurance set out in Annex II (MDD) is described in the said CE marking of Conformity Certificates issued and delivered by TÜV SUD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München - Germany.

The standard use to show compliance with Essential Requirement is

Medical Swabs and Applicators for Sample collection and preservation Microbiology Investigation with or without transport medium

This declaration is supported by the Quality System certification based on the standards UNI EN ISO 9001:2008 Quality System certificate with reference number 50 100 9777 issued on August 31, 2010 valid until August 30, 2013 delivered by TÜV Italia S.r.l., Gruppo TÜV Sud, Via Carducci 1225, pal. 23 20099 Sesto San Giovanni (MI) - Italy and EN ISO 13485:2003 quality System certificate with reference number Q1N 10 07 73936 002 issued on September 02, 2010 valid until September 01, 2013 and delivered by TÜV SUD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München - Germany.

This Declaration of Conformity covers MICROBIOLOGICAL SWABS as specified in the products list belonging to this declaration and is valid for all products concerned bearing the CE marking and manufactured at the following site :

*Copan Italia spa*  
*Via Perotti 10 – 25125 Italia*

**ISSUED DATE:** Brescia, 02 September 2010

**REVISION DATE:** Brescia, 13 May 2011

Stefania Triva  
Quality Assurance & Regulatory Affair Manager

A handwritten signature in blue ink, appearing to read "Stefania Triva".

Annex : product list TRANSYSTEM<sup>®</sup>, STERILE SWABS



**PRODUCT LIST**  
**TRANSYSTEM® ,STERILE SWABS IN TUBE**

This product list belong to declaration of Conformity identified by " swabs type " and specifies the CE marked products concerned that Copan Italia intends to distribute in conformity with the provisions of the Council Directive 93/42/ECC of 14 June 1993, and following updates, concerning Medical Device.

COPAN BASE N°	MDD SWABS DESCRIPTION	ADDING DATE
108C	SINGLE PLASTIC WITH AMIES WITHOUT CHARCOAL	01 SEPTEMBER 2004
110C	REGULAR ALLUMINIUM WIRE WITH AMIES WITHOUT CHARCOAL	01 SEPTEMBER 2004
111C	SINGLE PLASTIC WITH STUART WITHOUT CHARCOAL	01 SEPTEMBER 2004
114C	SINGLE PLASTIC WITH AMIES WITH CHARCOAL	01 SEPTEMBER 2004
116C	REGULAR ALLUMINIUM WIRE WITH AMIES WITH CHARCOAL	01 SEPTEMBER 2004
117C	SINGLE PLASTIC WITH STUART WITH CHARCOAL	01 SEPTEMBER 2004
124C	SOFT ALLUMINIUM WIRE WITH AMIES WITHOUT CHARCOAL	01 SEPTEMBER 2004
125C	SOFT ALLUMINIUM WIRE WITH AMIES WITH CHARCOAL	01 SEPTEMBER 2004
126C	SOFT ALLUMINIUM WIRE PLASTIC WITH AMIES LIQUID FORM	01 SEPTEMBER 2004
127C	SOFT ALLUMINIUM WIRE WITH STUART LIQUID FORM	01 SEPTEMBER 2004
132C	SINGLE PLASTIC WITH CARY BLAIR MEDIUM	01 SEPTEMBER 2004
134C	DOUBLE PLASTIC WITH AMIES WITHOUT CHARCOAL	01 SEPTEMBER 2004
136C	DOUBLE PLASTIC WITH AMIES WITH CHARCOAL	01 SEPTEMBER 2004
138C	DOUBLE PLASTIC WITH AMIES LIQUID FORM	01 SEPTEMBER 2004
139C	DOUBLE PLASTIC WITH STUART LIQUID FORM	01 SEPTEMBER 2004
140C	SINGLE PLASTIC WITH AMIES LIQUID FORM	01 SEPTEMBER 2004
141C	SINGLE PLASTIC WITH STUART LIQUID FORM	01 SEPTEMBER 2004
142C	REGULAR ALLUMINIUM WIRE PLASTIC WITH AMIES LIQUID FORM	01 SEPTEMBER 2004
143C	REGULAR ALLUMINIUM WIRE WITH STUART LIQUID FORM	01 SEPTEMBER 2004
150C	SINGLE WOOD SWAB RAYON TIP IN TUBE	01 SEPTEMBER 2004
155C	SINGLE PLASTIC SWAB RAYON TIP IN TUBE	01 SEPTEMBER 2004
160C	SINGLE ALLUMINIUM SWAB IN TUBE	01 SEPTEMBER 2004
167C	DOUBLE PLASTIC SWAB RAYON TIP IN TUBE	01 SEPTEMBER 2004
190C	FLEXIBLE TWISTED WIRE WITH AMIES WITHOUT CHARCOAL	01 SEPTEMBER 2004
191C	FLEXIBLE TWISTED WIRE PLASTIC WITH AMIES LIQUID FORM	01 SEPTEMBER 2004
192C	FLEXIBLE TWISTED WIRE WITH AMIES WITH CHARCOAL	01 SEPTEMBER 2004
128C	PAPER SWAB WITH AMIES WITHOUT CHARCOAL	07 NOVEMBER 2008
109C	SINGLE WOOD WITH AMIES WITHOUT CHARCOAL	26 NOVEMBER 2008
112C	SINGLE WOOD WITH STUART WITHOUT CHARCOAL	26 NOVEMBER 2008
113C	REGULAR ALLUMINIUM WIRE WITH STUART WITHOUT CHARCOAL	26 NOVEMBER 2008
115C	SINGLE WOOD WITH WITH AMIES WITH CHARCOAL	26 NOVEMBER 2008
118C	SINGLE WOOD WITH STUART WITH CHARCOAL	26 NOVEMBER 2008
119C	REGULAR ALLUMINIUM WIRE WITH STUART WITH CHARCOAL	26 NOVEMBER 2008
129C	PAPER SWAB WITH AMIES WITH CHARCOAL	26 NOVEMBER 2008
144C	SINGLE PLASTIC WITH LIQUID CHLAMYDIA	26 NOVEMBER 2008
145C	REGULAR ALLUMINIUM WIRE WITH LIQUID CHLAMYDIA	26 NOVEMBER 2008
146C	FLEXIBLE ALLUMINIUM WIRE WITH LIQUID CHLAMYDIA	26 NOVEMBER 2008
147C	SINGLE PLASTIC WITH LIQUID VIRAL MEDIUM	26 NOVEMBER 2008
148C	REGULAR ALLUMINIUM WIRE WITH LIQUID VIRAL MEDIUM	26 NOVEMBER 2008
149C	FLEXIBLE ALLUMINIUM WIRE WITH LIQUID VIRAL MEDIUM	26 NOVEMBER 2008
152C	CARBONATED SINGLE WOOD SWAB IN TUBE	26 NOVEMBER 2008
154C	SINGLE WOOD SWAB RAYON TIP IN TUBE	26 NOVEMBER 2008
157C	CARBONATED SINGLE PLASTIC SWAB IN TUBE	26 NOVEMBER 2008

**International Enquiries:** Copan Italia S.p.A.  
 Via F. Perotti, 10 – 25125 BRESCIA – Italy  
 Tel.: ++39 030 2687211 – Fax: ++39 030 2687206  
 E-mail: info@copanitalia.com – Web site: www.copanitalia.com  
 Capitale Sociale: € 600.000 int. vers.  
 Cod. Ident. IVA – VAT ID Nr. IT 01740560170

**U.S.A. Enquiries:** Copan Diagnostics Inc.  
 26055 Jefferson Avenue  
 Murrieta, California 92562, USA  
 Tel.: 800 216 4016 – 951 696 6957  
 Fax: 951 549 8850  
 E-Mail: copanswabs@aol.com



COPAN BASE N°	MDD SWABS DESCRIPTION	ADDING DATE
159C	SINGLE PLASTIC SWAB POLYESTER TIP IN TUBE	26 NOVEMBER 2008
162C	SINGLE ALLUMINUM SWAB POLYESTER TIP IN TUBE	26 NOVEMBER 2008
163C	SINGLE WOOD SWAB COTTON TIP IN TUBE	26 NOVEMBER 2008
164C	SINGLE PAPER SWAB IN TUBE	26 NOVEMBER 2008
168C	FLEXIBLE ALLUMINIUM WIRE IN TUBE	26 NOVEMBER 2008
170C	SINGLE PLASTIC SWAB RAYON TIP IN TUBE	26 NOVEMBER 2008
184C	MINITIP SINGLE PLASTIC RAYON TIP IN TUBE	26 NOVEMBER 2008
185C	MINITIP SINGLE PLASTIC POLYESTER TIP IN TUBE	26 NOVEMBER 2008
195CFE	FLEXIBLE TWISTED WIRE WITH STUART LIQUID FORM	26 NOVEMBER 2008
408C	M40 SINGLE PLASTIC WITH AMIES WITHOUT CHARCOAL	26 NOVEMBER 2008
414C	M40 SINGLE PLASTIC WITH AMIES WITH CHARCOAL	26 NOVEMBER 2008
451C	SINGLE WOOD SWAB RAYON TIP WITH VEGETAL PROTEIN IN TUBE	26 NOVEMBER 2008
456C	SINGLE PLASTIC SWAB RAYON TIP WITH VEGETAL PROTEIN IN TUBE	26 NOVEMBER 2008
172C	FLEXIBLE ALLUMINIUM WIRE RAYON TIP IN TUBE	01 FEBRUARY 2011
188C	MINITIP SINGLE PLASTIC POLYESTER TIP IN TUBE	01 FEBRUARY 2011

To all the base code here before listed any prefix or suffix added indicate only a customization of the packaging lay-out and/or cap color.

**ISSUED DATE:** Brescia, 02 September 2010

**REVISION DATE:** Brescia, 13 May 2011

Stefania Triva  
QA & RA Manager