

**EC-DECLARATION OF CONFORMITY**  
**Transystem™**  
**MEDICAL DEVICE**

**Manufacturer:** *Copan Italia S.p.A.*  
*Via Perotti, 10*  
*25125 Brescia, Italia*

**European Representative:** *N.A.*

**Product family:** *Fiber Swab Transport System - Transystem™*  
*(See the attached product list)*

**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 SÜD 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**  
**Transystem™**  
**TRANSYSTEM™ GEL CLASSIC**  
**TRANSYSTEM AMIES GEL**

<b>TRANSYSTEM AMIES GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>108C</b>	TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>108C.USE</b>	TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>108CSR</b>	TRANSYSTEM AMIES W/O CHARCOAL PLASTIC APP. RAYON TIPPED DOUBLE WRAPPED
<b>110C</b>	TRANSYSTEM AMIES W/O CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>110C.USE</b>	TRANSYSTEM AMIES W/O CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>114C</b>	TRANSYSTEM AMIES WITH CH PLASTIC APPLICATOR RAYON TIPPED
<b>114C.USE</b>	TRANSYSTEM AMIES WITH CH PLASTIC APPLICATOR RAYON TIPPED
<b>116C</b>	TRANSYSTEM AMIES W/CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>116C.USE</b>	TRANSYSTEM AMIES W/CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>124C.USE</b>	TRANSYSTEM AMIES W/O CH SOFT ALUMINIUM APPLICATOR RAYON TIPPED
<b>125C.USE</b>	TRANSYSTEM AMIES W/CH SOFT ALUMINIUM APPLICATOR RAYON TIPPED
<b>134C.USE</b>	TRANSYSTEM AMIES W/O CH DUAL SWAB PLASTIC APPLIC. RAYON TIPPED
<b>136C.USE</b>	TRANSYSTEM AMIES W/CH DUAL PLASTIC APPLICATOR RAYON TIPPED
<b>190C.USE</b>	TRANSYSTEM AMIES W/O CH. TWISTED APPLICATOR RAYON TIPPED
<b>192C.USE</b>	TRANSYSTEM AMIES WITH CH FLEXIBLE AL. APPLICATOR RAYON TIPPED
<b>108CC</b>	TRNASYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>TRANSYSTEM STUART GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>111C</b>	TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>111C.USE</b>	TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>113C.USE</b>	TRANSYSTEM STUART W/O CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>117C</b>	TRANSYSTEM STUART WITH CH PLASTIC APPLICATOR RAYON TIPPED
<b>117C.USE</b>	TRANSYSTEM STUART WITH CH PLASTIC APPLICATOR RAYON TIPPED
<b>119C.USE</b>	TRANSYSTEM STUART WITH CH ALUMINIUM APPLICATOR RAYON TIPPED

**TRANSYSTEM™ LIQUID CLASSIC**

<b>TRANSYSTEM AMIES LIQUID</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>126C.USE</b>	TRANSYSTEM LQ AMIES SOFT ALUMINIUM APPLICATOR RAYON TIPPED
<b>138C.USE</b>	TRANSYSTEM LQ AMIES DUAL APPLICATORS RAYON TIPPED
<b>140C.USE</b>	TRANSYSTEM LQ AMIES PLASTIC APPLICATOR RAYON TIPPED
<b>142C.USE</b>	TRANSYSTEM LQ AMIES ALUMINIUM APPLICATOR RAYON TIPPED
<b>191C.USE</b>	TRANSYSTEM LIQUID AMIES TWISTED APPLICATOR RAYON TIPPED
<b>TRANSYSTEM STUART LIQUID</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>139C.USE</b>	TRANSYSTEM LQ STUART DUAL PLASTIC APPLICATORS RAYON TIPPED
<b>141C.USE</b>	TRANSYSTEM LQ STUART PLASTIC APPLICATOR RAYON TIPPED
<b>143C.USE</b>	TRANSYSTEM LQ STUART ALUMINIUM APPLICATOR RAYON TIPPED
<b>TRANSYSTEM CARY-BLAIR</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>132C</b>	TRANSYSTEM CARY BLAIR MEDIUM PLASTIC APPLICATOR RAYON TIPPED
<b>132C.USE</b>	TRANSYSTEM CARY BLAIR MEDIUM PLASTIC APPLICATOR RAYON TIPPED
<b>TRANSYSTEM AMIES M40 GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>408C</b>	M40 TRANSYSTEM AMIES W/O CHARC. PLASTIC APPLICATOR RAYON TIPPED
<b>414C</b>	M40 TRANSYSTEM AMIES W/CH PLASTIC APPLICATOR RAYON
<b>434C</b>	M40 TRANSYSTEM AMIES W/O CHARCOAL DOUBLE PLASTIC APP. RAYON TIPPED
<b>1E023S</b>	M40 TRANSYSTEM AMIES W/O CHARC. PLASTIC APPLICATOR RAYON TIPPED BLUE CAP
<b>TRANSYSTEM CHLAMYDIA</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>144C</b>	CHLAMYDIA TRANSPORT SWAB PLASTIC APPLICATOR POLYESTER TIPPED
<b>145C</b>	CHLAMYDIA TRANSPORT SWAB ALUMINIUM APPLICATOR POLYESTER TIPPED
<b>TRANSYSTEM VIRAL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>147C</b>	VIRUS TRANSPORT MEDIUM PLASTIC APPLICATOR POLYESTER TIPPED
<b>147CV</b>	VIRUS TRANSPORT MEDIUM PLAST. APPLICATOR POLYEST. TIPPED GREEN CAP
<b>148C</b>	VIRUS TRANSPORT MED. ALUMINIUM APPLICATOR POLYESTER TIPPED

The following product codes are Copan Transystem™ with labelling customization:

<b>TRANSYSTEM AMIES GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>108C.MOH</b>	TRNASYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>108CF.LBT</b>	TRANS. AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED ORANGE CAP
<b>108CF.PH</b>	TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>108CFVL.FR</b>	TRANSYSTEM AMIES W/O CH PLASTIC APP. RAYON TIPPED VIOLET CAP
<b>114CF167K.IS</b>	TRANSYSTEM AMIES WITH CH 2 PLASTIC APPLICATORS RAYON TIPPED
<b>125CFE.LD</b>	TRANSYSTEM AMIES WITH CH SOFT ALUMINIUM APPLICATOR RAYON TIPPED
<b>8108CIS.US</b>	TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>8110CIS.US</b>	TRANSYSTEM AMIES W/O CH ALUMINIUM APPLICATOR RAYON TIPPED
<b>8114CIS.US</b>	TRANSYSTEM AMIES WITH CH PLASTIC APPLICATOR RAYON TIPPED
<b>8190CIS.US</b>	TRANSYSTEM AMIES W/O CH TWISTED APPLICATOR RAYON TIPPED
<b>TRANSYSTEM STUART GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>111CF.BM</b>	TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>111C.BR</b>	TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED
<b>TRANSYSTEM AMIES LIQUID</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>191C.Q</b>	TRANSYSTEM LIQUID AMIES TWISTED APPLICATOR RAYON TIPPED
<b>TRANSYSTEM AMIES M40 GEL</b>	
<b>CODE</b>	<b>DESCRIPTION</b>
<b>408C.IS</b>	M40 TRANSYSTEM AMIES W/O CHARCOAL PLASTIC APPLICATOR RAYON TIPPED
<b>408CTB.IS</b>	M40 TRANS.AMIES W/O CHARCOAL PLAST. APPLIC.RAYON TIPPED BLUE CAP

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, 25<sup>th</sup> May 2021

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Elisabetta Zanella  
Chief Regulatory Officer