

**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