

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: *26th May 2024*

PRODUCT LIST
Transystem™
TRANSYSTEM™ GEL CLASSIC
TRANSYSTEM AMIES GEL

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

TRANSYSTEM™ LIQUID CLASSIC

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

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

| TRANSYSTEM AMIES GEL | |
|---------------------------------|---|
| CODE | DESCRIPTION |
| 108C.MOH | TRNASYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED |
| 108CF.LBT | TRANS. AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED ORANGE CAP |
| 108CF.PH | TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED |
| 108CFVL.FR | TRANSYSTEM AMIES W/O CH PLASTIC APP. RAYON TIPPED VIOLET CAP |
| 114CF167K.IS | TRANSYSTEM AMIES WITH CH 2 PLASTIC APPLICATORS RAYON TIPPED |
| 125CFE.LD | TRANSYSTEM AMIES WITH CH SOFT ALUMINIUM APPLICATOR RAYON TIPPED |
| 8108CIS.US | TRANSYSTEM AMIES W/O CH PLASTIC APPLICATOR RAYON TIPPED |
| 8110CIS.US | TRANSYSTEM AMIES W/O CH ALUMINIUM APPLICATOR RAYON TIPPED |
| 8114CIS.US | TRANSYSTEM AMIES WITH CH PLASTIC APPLICATOR RAYON TIPPED |
| 8190CIS.US | TRANSYSTEM AMIES W/O CH TWISTED APPLICATOR RAYON TIPPED |
| TRANSYSTEM STUART GEL | |
| CODE | DESCRIPTION |
| 111CF.BM | TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED |
| 111C.BR | TRANSYSTEM STUART W/O CH PLASTIC APPLICATOR RAYON TIPPED |
| TRANSYSTEM AMIES LIQUID | |
| CODE | DESCRIPTION |
| 191C.Q | TRANSYSTEM LIQUID AMIES TWISTED APPLICATOR RAYON TIPPED |
| TRANSYSTEM AMIES M40 GEL | |
| CODE | DESCRIPTION |
| 408C.IS | M40 TRANSYSTEM AMIES W/O CHARCOAL PLASTIC APPLICATOR RAYON TIPPED |
| 408CTB.IS | 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, 25th May 2021

Place, Date of Print: Brescia, 12th October 2023

Elisabetta Zanella
Chief Regulatory Officer