

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

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Elisabetta Zanella
Chief Regulatory Officer