

**EC-DECLARATION OF CONFORMITY**  
**Transystem™ - Sarstedt**  
**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 "Transystem™ - Sarstedt")*

**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 SUD 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™ - Sarstedt**

<b>CODE</b>	<b>DESCRIPTION</b>
<b>80.1361</b>	Transystem Amies w/o ch plastic applicator rayon tipped
<b>80.1363</b>	Transystem Amies w/o ch aluminium applicator rayon tipped
<b>80.1362</b>	Transystem Amies with ch plastic applicator rayon tipped
<b>80.1366</b>	Transystem Amies with ch aluminium applicator rayon tipped
<b>80.1366.001</b>	Transystem Amies with ch flexible al. applicator rayon tipped

**Place, Date of Issue:** Brescia, 20<sup>th</sup> March 2020



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Elisabetta Zanella  
Chief Regulatory Officer