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

| | |
|---|---|
| **Manufacturer:** | *Copan Italia S.p.A.*<br>*Via Perotti, 10*<br>*25125 Brescia, Italia* |
| **European Representative:** | *N.A.* |
| **Product family:** | *Fiber Swab Transport System - Transystem™*<br>*(See the attached product list "Transystem™- Cepheid")* |
| **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***

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| **Notified Body:** | *TÜV SUD PRODUCT SERVICE GmbH,*<br>*Ridlerstraße 65, 80339 München-Germany,*<br>*Notified Body Identification Number 0123* |
| **EC Certificate(s):** | G1 073936 0014 |
| **Valid until:** | 1st September 2020 |

# PRODUCT LIST

## *TRANSYSTEM™ - Cepheid*

| CODE | DESCRIPTION |
|---|---|
| **900-0370** | Transystem LQ Stuart dual applicators breakable point 33mm |

**Place, Date of Issue:** Brescia, 18th September 2019

Elisabetta Zanella
Chief Regulatory Officer