



S GR11.1 DOC 110
REV05 OF 02/05/2024

CERTIFICATE OF STERILITY AND QUALITY ASSURANCE

N°
**24-
CRT0429
3**

COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE
139CFA	900-0370	241375900	25/12/2025

Device description :	TRANSYSTEM LQ/STUART DUAL APPLIC. WITH MOLDED BREAK POINT
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Goods have been irradiated by gamma radiation.
Sterilization procedure is validated in conformity with ISO 11135:2014 to guarantee the Sterility Assurance Level SAL 10⁻⁶

Goods has been manufactured according to the EN ISO 13485:2016 system.

Medium Visual Appearance and Mechanical Controls: passed according to internal SOP.

pH of the medium at 25°C acceptability limits 7.2 ± 0.3: passed

Microscopic Bioburden Specifications, maximum 2 micro-organisms per 20 microscopic fields at 10X100 magnification: passed.

Cultural Response: swabs were inoculated with the tester organisms (see the table) and placed in the medium. Recovery obtained after 24 hours at 20-25°C: passed.

TRANSYSTEM AMIES AND STUART CLEAR GEL AND WITH CHARCOAL	TRANSYSTEM AMIES AND STUART LIQUID	TRANSYSTEM CARY BLAIR
<i>N. gonorrhoeae</i> ATCC 43069	<i>N. gonorrhoeae</i> ATCC 43069	<i>C. jejuni</i> ATCC 33291
<i>B. fragilis</i> ATCC 25285	<i>S. pyogenes</i> ATCC 19615	<i>E. coli</i> ATCC 25922
<i>H. influenza</i> ATCC 10211	<i>H. influenzae</i> ATCC 10211	<i>S. flexneri</i> ATCC 12022
/	/	<i>Y. enterocolitica</i> ATCC 9610

All reported results were obtained following internal SOP instructions.

Copan Italia SpA certifies that all product quality requirements have been met and that all information stated above is correct.

Manufacturer: Copan Italia SpA, via F. Perotti 10, 25125 Brescia, Italy

29/10/2024

Certificate Date of Issue

Quality Representative
Copan Italia SpA
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