

 SGR11.1 DOC 122 Rev 02 21/03/2019	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 19- CRT04258
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COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE
8U004N.PH	8U004N.PH	191234000	31/07/2021

DEVICE DESCRIPTION:	Xpert Vaginal/Endocervical Specimen Collection Kit
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1. Packaging date: 17/07/2019
2. pH of the medium, acceptability limits pH 8,15 - 8,55 at 20,0-26,0 °C: passed
3. FLOQSwabs have been EO treated.
Biological Indicator control for EO treatment using *B. atrophaeus* 10⁶ sporestrip: no growth after validated incubation conditions at 37± 2°C.
4. Cleaning Swabs have been irradiated by gamma radiation.
The applied dose range is validated to guarantee the Sterility Assurance Level SAL 10⁻⁶.

All reported results were obtained at the time of lot release.
 Goods have been manufactured according to the ISO 13485:2016 system.
 By signing below, Copan Italia SpA certifies that the above quality requirements have been met and all information stated above is correct.

Made by COPAN ITALIA SpA, via F.Perotti 10, 25125 Brescia, Italy for CEPHEID
 Includes Flocked Swab made by COPAN FLOCK TECHNOLOGIES srl, via F. Perotti 18, 25125 Brescia, Italy

05/08/2019
 Certificate Date of Issue


 Chief Quality Officer
 Copan Italia SpA