

 S GR11.1 DOC 223 REV01 OF 23/10/2020	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 20- CRT07094
--	--	----------------------------------

COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE
8U004N.PH	8U004N.PH	202722900	31/10/2023

DEVICE DESCRIPTION:	Xpert Vaginal/Endocervical Specimen Collection Kit
----------------------------	--

1. Packaging date: 11/11/2020
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.

15/12/2020
Certificate Date of Issue


Chief Quality Officer
Copan Italia SpA
Via F.Perotti, 10 – 25125 Brescia (Italy)