

 SGR11.1 DOC 122 Rev 01 21/08/2017	<b>CERTIFICATE OF STERILITY AND QUALITY ASSURANCE</b>	<b>N° 19- CRT01310</b>
--	---	--------------------------------

COPAN CODE	CEPHEID CODE	LOT N°	EXP. DATE
8U004N.PH	SWAB/A-50	190235700	28/02/2021

<b>DEVICE DESCRIPTION:</b>	Xpert Swab Specimen Collection Kit A
----------------------------	--------------------------------------

1. Packaging date: 01/03/2019
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* 10<sup>6</sup> sporestrip: no growth after minimum 2 days at 35-37°C.
4. Cleaning Swabs have been irradiated by gamma radiation.  
The applied dose range is: 25-35KGY.

All reported results were obtained at the time of lot release.  
 Goods have been manufactured according to the ISO 13485 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

Copan Group Chief Quality Officer

Certificate Issue Date  
14/03/2019

