

 <p>S GR11.6 DOC 199 REV04 OF 02/05/2024</p>	CERTIFICATE OF QUALITY ASSURANCE	N° 24- CRT01949
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CODE	LOT.N°	EXP. DATE
50E010D01	50E010D01	2403829
		11/03/2027

DEVICE DESCRIPTION:	FLOQSwabs hDNA free – Buccal FLOQSwab 20mm bp in tube with Active Drying System
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Goods have been EO treated and are guaranteed free of amplifiable human DNA, detectable DNase and RNase.

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

DNase test procedure

Following internal SOP, FLOQSwabs™ hDNA free are saturated with a solution containing standard DNA ladder. DNA from solution exposed to the swabs must be intact.

RNase test procedure

Following internal SOP, FLOQSwabs™ hDNA free are saturated with a solution containing standard RNA ladder. RNA from solution exposed to the swabs must be intact.

Human DNA contamination test procedure

Following internal SOP swabs are extracted and a portion of the extract is tested with the Identifiler® Plus STR kit at 29 cycles on Applied Biosystems® Genetic Analyzer. A passing result is achieved if no reproducible, typeable peaks are detected above background levels within the read region for each extraction.

All reported results were obtained following internal SOP instructions and are guaranteed until peel opened.

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

06/05/2024

Certificate Date of Issue



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