

CERTIFICATE OF QUALITY ASSURANCE

N° 22-CRT05895

| CODE | | LOT.N° | EXP. DATE |
|-----------|-----------|---------|------------|
| 50E010D01 | 50E010D01 | 2218608 | 11/10/2025 |

| DEVICE DESCRIPTION: | FLOQSwabs hDNA free – Buccal FLOQSwab 20mm bp in tube | |
|---------------------|---|--|
| | with Active Drying System | |

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, FLOQSwabsTM 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, FLOQSwabsTM 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 at time of lot release 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.

23/11/2022

Certificate Date of Issue

Quality Representative Copan Italia SpA

Julies Gouera

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