



SGR11.1 DOC146 Rev 00 07/01/2016

CERTIFICATE OF STERILITY AND QUALITY ASSURANCE**N°
16/066508**

Code:	Lot n°	Expiration date
9E001S.PMS	11A811	30/09/2016

Device description:	Particle Measuring Systems SurCapt Kit for microbial surface environmental monitoring, composed by 15.0mL SurCapt vial filled with 10 ml of Tryptic Soy Broth and FLOQSwab in its original tube
---------------------	---

Quality manufacturing:

- **SurCapt™** Microbial Surface Detection Kits have been manufactured according to the ISO 13485 system.
- Sterilization procedure validated in conformity with ISO 11137.

Sterilization:

- SurCapt™ Microbial Surface Detection Kits have been gamma irradiated to assure Sterility Assurance Level of 10⁻⁶.
- Verification of the Irradiation Certificate of the lot: comply with the specifications.

Swab device and swab tube:

- Visual appearance and mechanical controls: passed according to internal SOP.
- SRK pH passed according to acceptability limits 7.0 ± 0.5 at 25°C.
- Swab released test: passed according to internal SOP. Release rate ≥ 70%. Test organism: *Escherichia coli* ATCC 25922.

TSB broth:

- Filling nominal volume: 10ml
- Media Composition: refer to technical data sheet
- TSB pH: passed according to acceptability limits 7.3 ± 0.3 at 25°C.
- TSB visual appearance clear and transparent: passed according to internal SOP.
- TSB TSE/BSE absence: comply

Fertility Cultural Response Control (TSB broth after gamma-irradiation):

Devices inoculated with the reference microorganisms (initial inoculum 10-100 viable microorganism).

Presence of Turbidity/Growth obtained after 24-72h hours incubation at 30-35°C (bacteria) and 72-120 hours at 20-25°C (yeast and mould).

Reference microorganisms:

- *Aspergillus brasiliensis* ATCC 16404
- *Bacillus subtilis* ATCC 6633
- *Candida albicans* ATCC 10231
- *Escherichia coli* ATCC 8739
- *Pseudomonas aeruginosa* ATCC 9027
- *Staphylococcus aureus* ATCC 6538

Functional baseline sensor response by GreenLight reader:

Oxygenated fluorescence decay reading (gamma irradiates SurCapt vials) ≤ 28 µsec: passed according to internal SOP.

De-oxygenated fluorescence decay reading (inoculated vials with initial inoculum 10-100 viable microorganism, by *Escherichia coli* ATCC 8739 and incubated at 30-35°C for 24h) > 28 µsec: passed according to internal SOP.

All the reported results are obtained at time of lot release following SOP's approved instructions.

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

SurCapt™ Kit uses GreenLight® Technology. GreenLight is a registered trademark of Luxcel BioSciences, Ltd.

22/04/2016

Certificate Date of Issue

Quality Assurance
Copan Italia SpA