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| <b>Product:</b> <b>BioCapt® Single-Use</b> Manufactured by Neomed srl | <b>Product Code:</b> 79001209 |
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| <b>Media:</b> | <b>TRYPTONE SOYA AGAR + NEUTRALIZERS</b><br>(Tryptone Soya Agar + 0.07% Lecithin + 0.5% Tween80 + 0.05% Sodiosulfate + 0.1% Histidine) |
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| <b>Lot Nr:</b><br>18B2103                      | <b>Date of Manufacturing:</b><br>21 Feb 2018 | <b>Expiry date :</b><br>21 Feb 2019     | <b>Storage Conditions:</b><br>2-25°C up to expire date |
| <b>Sterilization:</b> ≥25 KGy gamma irradiated |  | <b>Irradiation Certificate Nr:</b> 2051 | <b>Conforms</b>  |

### CHEMICAL / PHYSICAL TESTS:

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| <b>Appearance:</b> light amber coloured, clear to slightly opalescent gel forms in BioCapt device plates | <b>Conforms</b>                          |
| <b>pH specification:</b> 7.3 ± 0.2 at 25°C   | <b>pH result:</b> 7,3<br><b>Conforms</b> |
| <b>Filling media Volume:</b> 30 ml ± 1ml   | <b>Conforms</b>                          |
| <b>Media Composition:</b> TSA + neutralizers – BSE free (see technical data sheet cod 79001209)          | <b>Conforms</b>                          |

### MICROBIOLOGICAL TEST CONTROLS:

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| <b>Sterility Control - Absence of contamination</b><br>At the following incubation conditions (performed before gamma irradiation):<br>32.5 ± 2.5°C aerobic for 7 days<br>22.5 ± 2.5°C aerobic for 7 days | <b>Conforms</b> |
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| <b>Fertility - Growth Promotion test</b> ( performed after gamma irradiation): | <b>Conforms</b> |
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| Control strain                       | Medium inoculation level     | Incubation Conditions       | Recovery Specifications | Recovery Results | Cultural Response |
|--------------------------------------|------------------------------|-----------------------------|-------------------------|------------------|-------------------|
| <i>E. coli</i><br>ATCC 8739          | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70% ≤ R% ≤ 200%         | 86,1%            | <b>Conforms</b>   |
| <i>P. aeruginosa</i><br>ATCC 9027    | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70% ≤ R% ≤ 200%         | 100,6%           | <b>Conforms</b>   |
| <i>S. aureus</i><br>ATCC 6538        | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70% ≤ R% ≤ 200%         | 105,0%           | <b>Conforms</b>   |
| <i>B. subtilis</i><br>ATCC 6633      | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70% ≤ R% ≤ 200%         | 82,1%            | <b>Conforms</b>   |
| <i>C. albicans</i><br>ATCC 10231     | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200%         | 100,0%           | <b>Conforms</b>   |
| <i>A. brasiliensis</i><br>ATCC 16404 | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70% ≤ R% ≤ 200%         | 88,8%            | <b>Conforms</b>   |

**GROWTH PROMOTION TEST** IN ACCORDANCE TO HARMONISED EP – USP PHARMACOPOEIAS CHAPTER, BY QUANTITATIVE SURFACE PLATING METHOD.

**RECOVERY:** RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES X 100/CFU ENUMERATION ON REFERENCE TESTS.

**REFERENCE MEDIUM** FOR RECOVERY TESTS: TRYPTIC SOYA AGAR FOR ALL BACTERIA AND SABOURAUD DEXTROSE AGAR FOR YEAST & MOLD SPECIES.

**ATCC** IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION.

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| <b>Lot Status:</b> <b>Approved</b> | <b>Lot Approval Date:</b> 03 Apr 2018 |
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| <b>Quality Control Manager:</b> Dott.ssa Cinzia Bovio | <b>Signature:</b>  |
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