1. Form I: Shipping to Radiation

**Environmental tests shall be performed, according to procedure QC-6.4-1, for each of the cleaning cycle batches of NeuroProbes and/ or cannulas and/ or cables.**

**Cleaning shall be performed according to cleaning procedure QC-7.5-2.**

**Samples for Bioburden testing will be selected for each of the cleaning cycle batches.**

**Test reports shall be recorded in this form and shall be retained with each batch records.**

## Environmental Test Results

* + 1. Environmental Sampling shall be performed after batch cleaning cycle is completed.
    2. Fill in test results details for the contact and air plates samples test reports as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Report No/ date** | **Report results** | **Comments** |
| Table sample (TSA) # 1 |  | ☐ Pass  ☐ Fail |  |
| Table sample (TSA) # 2 | ☐ Pass  ☐ Fail |  |
| Table sample (TSA) # 3 | ☐ Pass  ☐ Fail |  |
| Table sample (SDA) # 1 | ☐ Pass  ☐ Fail |  |
| Table sample (SDA) # 2 | ☐ Pass  ☐ Fail |  |
| Table sample (SDA) # 3 | ☐ Pass  ☐ Fail |  |
| Air sample (TSA) # 4 |  | ☐ Pass  ☐ Fail |  |
| Air sample (SDA) # 4 | ☐ Pass  ☐ Fail |  |

## Bioburden Test Samples

* + 1. Sampling items for Bioburden tests, according to procedure QC-7.5-2.
    2. Fill in the table below for all samples bioburden test reports.

**Acceptance criteria:**

NeuroProbe / Cannula:

Bioburden ≤ 10 CFU/sample

Environmental Samples ≤ 10 CFU/sample

Electrode cable /AlphaProbe cable / LeadConfirm Cable/ Adaptor:

Bioburden ≤ 100 CFU/sample

Environmental Samples ≤ 100 CFU/sample

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test**  **Sample** | **Sample type** | **Sampled items from batch/ Lot #** | **Report No/ date** | **Report results Pass/ Fail** | **Comments** |
| Box # 1 | ☐NeuroProbe  ☐Cannula  ☐ LeadConfirm cable  ☐ LeadConfirm Adaptor  ☐ AlphaProbe cable  ☐ Electrode cable |  |  | ☐ Pass  ☐ Fail |  |
| Box # 2 | ☐NeuroProbe  ☐Cannula  ☐ LeadConfirm cable  ☐ LeadConfirm Adaptor  ☐ AlphaProbe cable  ☐ Electrode cable |  |  | ☐ Pass  ☐ Fail |  |
| Box # 3 | ☐NeuroProbe  ☐Cannula  ☐ LeadConfirm cable  ☐ LeadConfirm Adaptor  ☐ AlphaProbe cable  ☐ Electrode cable |  |  | ☐ Pass  ☐ Fail |  |
| Box # 4 | ☐NeuroProbe  ☐Cannula  ☐ LeadConfirm cable  ☐ LeadConfirm Adaptor  ☐ AlphaProbe cable  ☐ Electrode cable |  |  | ☐ Pass  ☐ Fail |  |

## Peel Test Samples

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Report No/ date** | **Pass/ Fail** | **Comments** |
| Pouch # 1 |  | ☐ Pass  ☐ Fail |  |
| Pouch # 2 |  | ☐ Pass  ☐ Fail |  |

(Acceptance criteria: see the laboratory report)

## Applicable Batches

* + 1. Please fill in all details of batches that belong to the cleaning cycle in section 2.1.

| **Sterile products** | | | |
| --- | --- | --- | --- |
| **Catalog Number** | **Description (NeuroProbe/ Cannula/electrode Cable/ AlphaProbe cable/ LeadConfirm cable/ LeadConfirm Adaptor)** | **Batch/ Lot Number** | **Boxes Number** |
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* + 1. **Release for sterilization**

Based on test results in sections 2.1, 2.2 and 2.3, I hereby approve the release for sterilization of all batches in section 2.4.1.

|  |  |
| --- | --- |
| ☐Release | ☐ Not Released |

* + 1. Fill in all details of batches that belong to the cleaning cycle in section 2.1

| **Non-sterile products** | | | |
| --- | --- | --- | --- |
| **Catalog Number** | **Description (NeuroProbe/ Cannula/AlphaProbe cable LeadConfirm cable/ LeadConfirm Adaptor)** | **Batch/ Lot Number** | **Boxes Number** |
|  |  |  |  |
|  |  |  |  |
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* + 1. **Non sterile Batches Release**

Based on test results in sections 2.1 and 2.2, I hereby approve the release of all batches in section 2.4.3.

Release Not release

## Approvals

Approve the Batches if all the tests above filled and passed

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Signature** | **Date** |
| **Performed By** |  |  |  |
| **Approved By** |  |  |  |