

**Company:** Esco Medical Technologies, UAB  
**Address:** Gamybos g. 2, Ramuciai, Kauno r., 54468 Lithuania  
**Name:** CultureCoin®  
**REF:** 1821493  
**LOT:** 070425  
**Batch size:** 2200 pcs

This certificate certifies that the product indicated above has been tested in accordance with the following test methods and meets its specifications.

**Method/ test description:**

| Purpose                                   | Method/ test                        | Description   |
|---|-------------------------------------|---|
| <b>Sterility</b>                          | Gamma irradiation                   | Irradiation is performed in accordance with ISO 11137:2015, ISO 13485:2016, and MDR 2017/745 requirements.                  |
| <b>Endotoxin determination</b>            | LAL (Limulus Amebocyte Lysate) test | The test is performed according to USP <85>, USP <161>, and ISO 10993-5:2009.   |
| <b>Package integrity check</b>            | Visual package inspection           | Inspection for external defects performed according to WI 7.5.1.5 „CultureCoin dishes packaging“.                           |
| <b>Dish integrity check</b>               | Visual dish inspection              | Inspection of dish condition performed according to WI 7.5.1.3 „Visual inspection of CultureCoin dishes“.                   |
| <b>Plasma effectiveness determination</b> | Surface energy test                 | The surface energy (DYNE) test is performed according to working instruction WI 8.2.6.22 „Surface Energy Test (DYNE Test)“. |
| <b>Biocompatibility</b>                   | MEA (Mouse Embryo Assay) test       | Biocompatibility was evaluated by assessing embryo toxicity using the MEA test, according to WI 8.2.6.5 „MEA test“.         |

**Method/ test results:**

| Method/ test                        | Criteria                               | Result           | Pass/Fail | Ref. No.          |
|-------------------------------------|--|------------------|-----------|-------------------|
| Gamma irradiation                   | 25-50 kGy                              | 31,4 - 39,7 kGy  | Pass      | B250149           |
| LAL (Limulus Amebocyte Lysate) test | <= 20 EU/device                        | <0,500 EU/device | Pass      | LAL.024.1119.2025 |
| Visual package inspection           | No visible packaging defects           | No defects       | Pass      | MEA-2025.04.16-00 |
| Visual dish inspection              | No visible dish defects                | No defects       | Pass      |                   |
| Surface energy test                 | No droplets formatted                  | No droplets      | Pass      |                   |
| MEA (Mouse Embryo Assay) test       | Average blastocyst formation rate >80% | 96,7 %           | Pass      |                   |

**Certificate issued by:**

Quality engineer

Position

Gediminas Zubras

Name Surname

Signature

UAB

Date

(dd/mm/yyyy)

24/04/2025

