

Company: Esco Medical Technologies, UAB
Address: Gamybos g. 2, Ramučiai, Kauno r., 54468 Lithuania
Name: CultureCoin®
REF: 1821493
LOT: 020326
Expiration date (yyyy-mm-dd) 2028-03-02
Batch size: 5250 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 |
|---|-------------------------------------|---|
| Sterility | Gamma irradiation | Irradiation is performed in accordance with ISO 11137:2015, ISO 13485:2016, and MDR 2017/745 requirements. |
| Endotoxin determination | LAL (Limulus Amebocyte Lysate) test | The test is performed according to USP <85>, USP <161>, and ISO 10993-5:2009. |
| Package integrity check | Visual package inspection | Inspection for external defects performed according to WI 7.5.1.5 „CultureCoin dishes packaging“. |
| Dish integrity check | Visual dish inspection | Inspection of dish condition performed according to WI 7.5.1.3 „Visual inspection of CultureCoin dishes“. |
| Plasma effectiveness determination | Surface energy test | The surface energy (DYNE) test is performed according to working instruction WI 8.2.6.22 „Surface Energy Test (DYNE Test)“. |
| Biocompatibility | 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 | 30.0 – 38.0 kGy | Pass | B260100 |
| LAL (Limulus Amebocyte Lysate) test | <= 20 EU/device | <0.500 EU/device | Pass | LAL.026.240.2026 |
| Visual package inspection | No visible packaging defects | No defects | Pass | MEA-2026.03.07-00 |
| 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

Akvilė Brusokaitė
Name Surname


Signature

12/03/2026
Date
(dd/mm/yyyy)