

	Certificate of conformity for CultureCoin	Dok. / Ref.	F 8.2.6.8
		Leidimo Nr. / Issue No.	1.0
		Data / Date	14/04/2025

**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)

