Company: Esco Medical Technologies, UAB
Address: Gamybos g. 2, Ramuciai, Kauno r., 54468 Lithuania
Name: CultureCoin®
REF: 1821493
LOT: 070725
Batch size: 5625 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	30,2-37,2 kGy	Pass	B250281
LAL (Limulus Amebocyte Lysate) test	<= 20 EU/device	<0,722 EU/device	Pass	LAL.024.2093.2025
Visual package inspection	No visible packaging defects	No defects	Pass	MEA-2025.06.18-01
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) | Reda Rulinskaitė (Name Surname) | Signature | 23/06/2025 (Date (dd/mm/yyyy))

LIETUVOS RESPUBLIKA UAB „Esco Medical Technologies" KAUNAS