

## **CERTIFICATE OF QUALITY**

ITEM name and code #4220 IUI Plus - Intra-Uterine Insemination Cannula with mandrel

**LOT NUMBER** 20210113

**EXPIRY DATE** 13 January 2025

STERILIZATION DATE 15 January 2021

STERILIZATION TECHNIQUE Gamma Irradiation

STERILIZATION DOSE 22,5 - 45 kGy

## QUALITY CONTROL TESTING PROCEDURES

TEST	SPECIFICATION	CONCLUSION	
Endotoxin Assay (LAL)	<1.0 EU/device	Pass *	
TEST	SPECIFICATIONS	CONCLUSION	
Mouse Embryo Assay (MEA)	> 80%	Pass *	
expressed as day 5 expanded blastocyst stage			

 $<sup>^{*}</sup>$  LAL and MEA results are conform the internal quality control procedure in which testing is conducted based on a representative sampling plan

Merve Toprak Signature date:

Gynétics Medical Products N.V. 9 February 2021