

## **CERTIFICATE OF QUALITY**

ITEM name and code #4220 IUI Memo - Intra-Uterine Insemination Catheter/Cannula with memory

**LOT NUMBER** 20210929

**EXPIRY DATE** 29 September 2025

STERILIZATION DATE 4 October 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 blasto stage	cyst		

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

29 October 2021

Merve Toprak Signature date:

Gynétics Medical Products N.V.