o-Medical-Products



## **CERTIFICATE OF QUALITY**

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

**LOT NUMBER** 20220810

**EXPIRY DATE** 10 August 2026

**STERILIZATION DATE** 12 August 2022

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. 5 September 2022