o-Medical-Products



CERTIFICATE OF QUALITY

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

LOT NUMBER 20231206

EXPIRY DATE 6 December 2027

STERILIZATION DATE 23 December 2023

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		

^{*} 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. 25 January 2024