o-Medical-Products



CERTIFICATE OF QUALITY

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

LOT NUMBER 20231108

EXPIRY DATE 8 November 2027

STERILIZATION DATE 11 November 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. 29 November 2023