o-Medical-Products



CERTIFICATE OF QUALITY

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

LOT NUMBER 20240522

EXPIRY DATE 22 May 2028

STERILIZATION DATE 26 June 2024

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. 23 July 2024