o-Medical-Products



CERTIFICATE OF QUALITY

ITEM name and code #4220 IUI Plus - Intra-Uterine Insemination Cannula with mandrel

LOT NUMBER 20241016

EXPIRY DATE 16 October 2028

STERILIZATION DATE 19 October 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

Begum Gungormus

Signature date:

Gynétics Medical Products N.V.

5 November 2024