o-Medical-Products



CERTIFICATE OF QUALITY

ITEM name and code #4225 Smooze - Intra-Uterine Insemination Catheter/Cannula Soft

LOT NUMBER 20240924

EXPIRY DATE 24 September 2028

STERILIZATION DATE 1 October 2024

STERILIZATION TECHNIQUE Gamma Irradiation

Biological Indicator testing: no growth of organisms

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 blastocys stage	t	

^{*} 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.

16 October 2024