O-Medical-Products:cs



CERTIFICATE OF QUALITY

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

LOT NUMBER 20231115

EXPIRY DATE 15 November 2027

STERILIZATION DATE 25 November 2023

STERILIZATION TECHNIQUE Ethylene Oxide

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 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.

12 December 2023