

CERTIFICATE OF QUALITY

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

LOT NUMBER 20200901

EXPIRY DATE 1 September 2024

STERILIZATION DATE 5 September 2020

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) <i>expressed as day 5 expanded blastocyst stage</i>	> 80%	Pass *

* LAL and MEA results are conform the internal quality control procedure in which testing is conducted based on a representative sampling plan



Merve Toprak
Gynétiks Medical Products N.V.

Signature date:
29 September 2020