

CERTIFICATE OF QUALITY

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

LOT NUMBER 20191120

EXPIRY DATE 20 November 2023

STERILIZATION DATE 24 November 2019

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 blasto stage	ocyst		

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

Greetje Hermans

Signature date:

Gynétics Medical Products N.V.

2 January 2020