o-Medical-Products



## **CERTIFICATE OF QUALITY**

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

**LOT NUMBER** 20250409

**EXPIRY DATE** 9 April 2029

STERILIZATION DATE 14 April 2025

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		

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

Signature date:

Gynétics Medical Products N.V.

Mirjam Smeets

12 May 2025