

CERTIFICATE OF QUALITY

ITEM name and code	#4220 IUI - Intra-Uterine Insemination Catheter/Cannula
LOT NUMBER	20210104
EXPIRY DATE	4 January 2025
STERILIZATION DATE	15 January 2021
STERILIZATION TECHNIQUE	Gamma Irradiation
STERILIZATION DOSE	22,5 - 45 kGy

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:

9 February 2021