

CERTIFICATE OF QUALITY

ITEM name and code #4220 IUI - Intra-Uterine Insemination Catheter/Cannula

LOT NUMBER 20210105

EXPIRY DATE 5 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)	> 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

Merve Toprak

Signature date:

Gynétics Medical Products N.V.

9 February 2021