

CERTIFICATE OF QUALITY

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

LOT NUMBER 20191218

EXPIRY DATE 18 December 2023

STERILIZATION DATE 22 December 2019

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 blaste 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.

22 January 2020