

CERTIFICATE OF QUALITY

ITEM name and code #4220 IUI Plus - Intra-Uterine Insemination Cannula with mandrel

LOT NUMBER 20200108

EXPIRY DATE 8 January 2024

STERILIZATION DATE 11 January 2020

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 blast 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. 5 February 2020