

CERTIFICATE OF QUALITY

ITEM name and code	#4220 IUI Memo - Intra-Uterine Insemination Catheter/Cannula with memory
LOT NUMBER	20200930
EXPIRY DATE	30 September 2024
STERILIZATION DATE	24 October 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) <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:
17 November 2020