

CERTIFICATE OF QUALITY

decs

ITEM name and code	#4220 IUI Memo - Intra-Uterine Insemination Catheter/Cannula with memory
LOT NUMBER	20211207
EXPIRY DATE	7 December 2025
STERILIZATION DATE	30 December 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 blastc 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 Gynétics Medical Products N.V. Signature date: 26 January 2022