eurofins | BioPharma Product Testing

SPONSOR	GERMO SpA		
	Via Giotto 19/21		
	20032 Cormano (MI)		
	ITALY		
TEST METHOD	EN 14476:2013+A1:2015- Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1).		
TEST SAMPLE			
PRODUCT NAME	*FT08 DM DISINFETTANTE SUPERFICI*		
MATRIX OF THE PRODUCT	Medical Device		
BATCH N.	N183988	CODE	Not provided
MANUFACTURING DATE	Not provided	EXPIRY DATE	31-May-21
MANUFACTURER	GERMO SpA		
COMPOSITION (ACTIVE INGREDIENT)	See Attachment N.1		
MATERIAL ITEM ALIQUOT	ST-STM-IJE2-18-184-0124:a		
PARCEL REGISTRATION NUMBER	IP-LV-2018159-AAS	RECEIVING DATE	08-Jun-18
ANALYSIS STARTING DATE	09-Jul-18	**ANALYSIS ENDING DATE**	16-Jul-18
EXPERIMENTAL CONDITIONS			
TEST TEMPERATURE	20°C ±1°C		
CONCENTRATIONS	80%- 50%-25% Test item dilutions were prepared 1.25 times the final test concentrations using water for injection.		
CONTACT TIME	5 minutes		
INACTIVATION OF THE PRODUCT	Filtration with S400 HR columns MicroSpinTM (and iced culture Medium)		
INTERFERING SUBSTANCES	Bovine serum albumin (BSA) and sheep erythrocytes with a final concentration of 0.3% (simulating dirty conditions).		
INCUBATION TEMPERATURE	37°C ±1°C (with 5% CO_2)		
TEST STRAIN	*Vaccinia virus (Strain MVA) ATCC VR-1508*		
CELL LINE	*BHK-21 ATCC CCL-10*		
VALIDITY AND EFFICACY CRITERIA	***Check of cytotoxicity of the test item*** The test item is cytotoxic at the concentrations tested so the entire test was carried out by means of filtration, but a residual cytotoxicity was observed again on both cell lines with the concentrations of 80%. However, the cytotoxicity of the		