



BioPharma
Product Testing



LAB N° 0032 L

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SPONSOR	WOW KEMICAL SRL		
	VIA SILVIO TRAVAGLIA, 14		
	35043, MONSELICE (PD)		
	ITALY		
TEST METHOD	EN 14476:2013+A2:2019 / UNI EN 14476:2019 - 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 ITEM			
PRODUCT NAME (*)	MICRO OXIGERM		
MATRIX OF THE PRODUCT (*)	Biocide and Antimicrobials		
BATCH (*)	03/2020	CODE (*)	MICRO OXIGERM concentrato REV.1A
MANUFACTURING DATE (*)	06-May-2020	EXPIRY DATE (*)	06-May-2023
MANUFACTURER	Not provided		
ACTIVE INGREDIENT (*)	Hydrogen peroxide 24% neat		
MATERIAL ITEM ALIQUOT	LV-MAT-FOV7-20-119-0919:a		
PARCEL REGISTRATION N.	IP-LV-2020129-AEN	RECEIVING DATE	08-May-2020
STORAGE CONDITIONS (*)	Room Temperature (20°C ± 5°C)		
(*) INFORMATION PROVIDED BY THE SPONSOR			
ANALYSIS STARTING DATE	12-May-2020	ANALYSIS ENDING DATE	25-May-2020
EXPERIMENTAL CONDITIONS			
TEST TEMPERATURE	25°C ± 1°C		
CONCENTRATIONS	33% - 16.6% - 1.66% The test item dilutions have been prepared 1.25 times higher than the final tested concentrations, using hard water. The dilutions were opaque and homogeneous. Test item dilution was stable throughout test (no precipitation in the test mixture).		
PRODUCT APPEARANCE	Transparent liquid		
CONTACT TIME	5 minutes		
INACTIVATION OF THE PRODUCT	Filtration with S400 HR columns MicroSpin™ (and iced culture Medium) Considering the composition of the test item, catalase from Micrococcus lysodeikticus has been added to the medium, proportionally to the final tested H ₂ O ₂ concentration (1 U corresponds to the amount of enzyme which decomposes 1µmol H ₂ O ₂ per minute at pH 7.0 and 25°C).		
INTERFERING SUBSTANCE	Bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions for the medical area)		
INCUBATION TEMPERATURE	37°C ±1°C (with 5% CO ₂)		



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TEST VIRUSES	<i>Poliovirus Type 1 LSc-2ab</i> (RVB-1260) <i>Adenovirus Type 5</i> (ATCC VR-5) <i>Murine norovirus, strain S99</i> (RVB-651)
CELL LINES	<i>HeLa</i> (ATCC CCL-2) <i>RAW 264.7</i> (ATCC TIB-71)
RESULTS	See Addendum N.1
CONCLUSIONS	VIRUCIDAL at test concentration of 16.6%, after 5 minutes of contact time, in the adopted test conditions, using bovine serum albumin at the final concentration of 0.3 g/L (0.03% - simulating clean conditions for the medical area).
ADDENDUM	N. 1: RAW DATA ELABORATION (33 PAGES)

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Reviewed and electronically signed for Technical Supervisor Approval by
Elisa Anna Maccagni, Employee
for Eurofins Biolab Srl, on 29-May-2020 12:22:38 UTC+02:00

	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 1 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità (Cytotoxicity)
 Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26.05.20

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Revision: 1	Local reference: Mod. PS/MIC/112.E
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Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità dopo filtrazione (Cytotoxicity after filtration)
Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
	F	0	0	0	0	0	0	0	0	0	0
	G	0	0	0	0	0	0	0	0	0	0
	Endpoint	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **0,50**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26-05-20Sigla Approver e data (Approver signature and date): BE 26/5/20

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Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Poliovirus Type 1 LSc-2ab

Titolazione virus (Virus Titration)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Poliovirus Type 1 LSc-2ab	B	0	4	4	4	3	3	2	0	0	0
	C	0	4	4	4	3	3	2	0	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	2	0	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Titolazione virale dopo filtrazione (Virus Titration after filtration)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Poliovirus Type 1 LSc-2ab	B	0	4	4	4	3	3	2	0	0	0
	C	0	4	4	4	3	3	2	0	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	2	0	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Reduction:

0,00

VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26-05-20

Sigla Approver e data (Approver signature and date): GP 28/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo sensibilità al virus (Control of virus sensitivity)
Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
PBS	B	0	4	4	4	3	3	2	1	0	0
	C	0	4	4	4	3	3	2	0	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	2	0	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	16,7	0,0	0,0
60 min											

Cell destruction:

VALID

Log TCID50: 6,67 ± 0,346

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	4	3	3	1	0	0	0
	C	0	4	4	4	3	3	1	0	0	0
	D	0	4	4	4	3	3	1	0	0	0
	E	0	4	4	4	3	3	1	0	0	0
	F	0	4	4	4	3	3	1	0	0	0
	G	0	4	4	4	3	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	83,3	0,0	0,0	0,0
33,0% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50: 6,33 ± 0,346

Reduction: 0,34 VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	4	3	3	2	0	0	0
	C	0	4	4	4	3	3	1	0	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	1	0	0	0
	F	0	4	4	4	3	3	1	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0
16,6% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50: 6,50 ± 0,000

Reduction: 0,17 VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	4	3	3	2	0	0	0
	C	0	4	4	4	3	3	2	0	0	0
	D	0	4	4	4	3	3	1	0	0	0
	E	0	4	4	4	3	3	2	0	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0
1,66% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50: 6,50 ± 0,000

Reduction: 0,17 VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26-05-20

Sigla Approver e data (Approver signature and date): GH 28/05/20

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		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)

Citotossicità riferimento (Reference Cytotoxicity)

Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
Formaldeide (Formaldehyde) 0,7% PBS	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: VALID
 Log TCID50: 2,50

Virus Control (Virus control)

Hela ATCC CCL-2

Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 0 min	B	0	4	4	4	3	3	0	0	0	0
	C	0	4	4	4	3	3	1	0	0	0
	D	0	4	4	4	3	3	0	0	0	0
	E	0	4	4	4	3	3	0	0	0	0
	F	0	4	4	4	3	3	0	0	0	0
	G	0	4	4	4	3	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	16,7	0,0	0,0	0,0

 Cell destruction: VALID
 Log TCID50: 6,67 ± 0,346

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 60 min	B	0	4	4	4	3	2	0	0	0	0
	C	0	4	4	4	3	2	0	0	0	0
	D	0	4	4	4	3	2	0	0	0	0
	E	0	4	4	4	3	3	0	0	0	0
	F	0	4	4	4	3	2	0	0	0	0
	G	0	4	4	4	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

 Cell destruction: VALID
 Log TCID50: 6,50 ± 0,000

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mu 26.05.20Sigla Approver e data (Approver signature and date): De 28/05/20

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ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)

Hela ATCC CCL-2

Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 30 min	B	0	4	3	1	0	0	0	0	0	0
	C	0	4	3	1	0	0	0	0	0	0
	D	0	4	3	1	0	0	0	0	0	0
	E	0	4	3	1	0	0	0	0	0	0
	F	0	4	3	1	0	0	0	0	0	0
	G	0	4	3	1	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

4,50

±

0,000

Reduction:

2,00

±

0,000

PASS

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 60 min	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

3,50

±

0,000

Reduction:

3,00

±

0,000

PASS

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26-05/20

Sigla Approver e data (Approver signature and date): JE 28/05/20

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Virus Control (Virus control)

Hela ATCC CCL-2

Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration 0 min	B	0	4	4	4	3	3	0	0	0	0
	C	0	4	4	4	3	3	0	0	0	0
	D	0	4	4	4	3	3	0	0	0	0
	E	0	4	4	4	3	3	0	0	0	0
	F	0	4	4	4	3	3	0	0	0	0
	G	0	4	4	4	3	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration Maximum contact time tested	B	0	4	4	4	3	2	0	0	0	0
	C	0	4	4	4	3	2	0	0	0	0
	D	0	4	4	4	3	2	0	0	0	0
	E	0	4	4	4	3	2	0	0	0	0
	F	0	4	4	4	3	2	0	0	0	0
	G	0	4	4	4	3	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MA 26-05-20

Sigla Approver e data (Approver signature and date): JH 28/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 8 / 38
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo soppressione attività prodotto (Control of suppression of product's activity)

Hela ATCC CCL-2

Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	2	0	0	0	0
	C	0	4	4	3	2	2	0	0	0	0
	D	0	4	4	3	2	2	0	0	0	0
	E	0	4	4	3	2	2	0	0	0	0
	F	0	4	4	3	2	2	0	0	0	0
	G	0	4	4	3	2	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Reduction:

0,00

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	2	0	0	0	0
	C	0	4	4	3	2	2	0	0	0	0
	D	0	4	4	3	2	2	0	0	0	0
	E	0	4	4	3	2	2	0	0	0	0
	F	0	4	4	3	2	2	0	0	0	0
	G	0	4	4	3	2	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Reduction:

0,00

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	2	0	0	0	0
	C	0	4	4	3	2	2	0	0	0	0
	D	0	4	4	3	2	2	0	0	0	0
	E	0	4	4	3	2	2	0	0	0	0
	F	0	4	4	3	2	2	0	0	0	0
	G	0	4	4	3	2	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Reduction:

0,00

VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26.05.20

Sigla Approver e data (Approver signature and date): [Signature] 28/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 9 / 38
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Procedura test (Test procedure)

Hela ATCC CCL-2

Poliovirus Type 1 LSc-2ab

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

2,50

±

0,000

Log reduction:

4,00

±

0,000

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

2,50

±

0,000

Log reduction:

4,00

±

0,000

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 5 min	B	0	4	4	3	3	0	0	0	0	0
	C	0	4	4	3	3	0	0	0	0	0
	D	0	4	4	3	3	0	0	0	0	0
	E	0	4	4	3	3	0	0	0	0	0
	F	0	4	4	3	3	0	0	0	0	0
	G	0	4	4	3	3	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

5,50

±

0,000

Log reduction:

1,00

±

0,000

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MA 26.05/20Sigla Approver e data (Approver signature and date): DA 28/05/20

	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 10 / 38
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Result summary**Attività virucida (Virucidal activity)**
Poliovirus Type 1 LSc-2ab

Prodotto (Product)	MICRO OXIGERM	
Sostanza interferente (Interfering substance)	BSA 0.03% final concentration	
Tempo di contatto (Contact time)	5 min	
Concentrazione (Concentration)	Riduzione Log (Log Reduction)	Status
33,0%	4 ± 0	PASS
16,6%	4 ± 0	PASS
1,66%	1 ± 0	FAIL

Data verifica Approver (Approver verification date): 25/05/20

Sigla Approver e data (Approver signature and date): Be 25/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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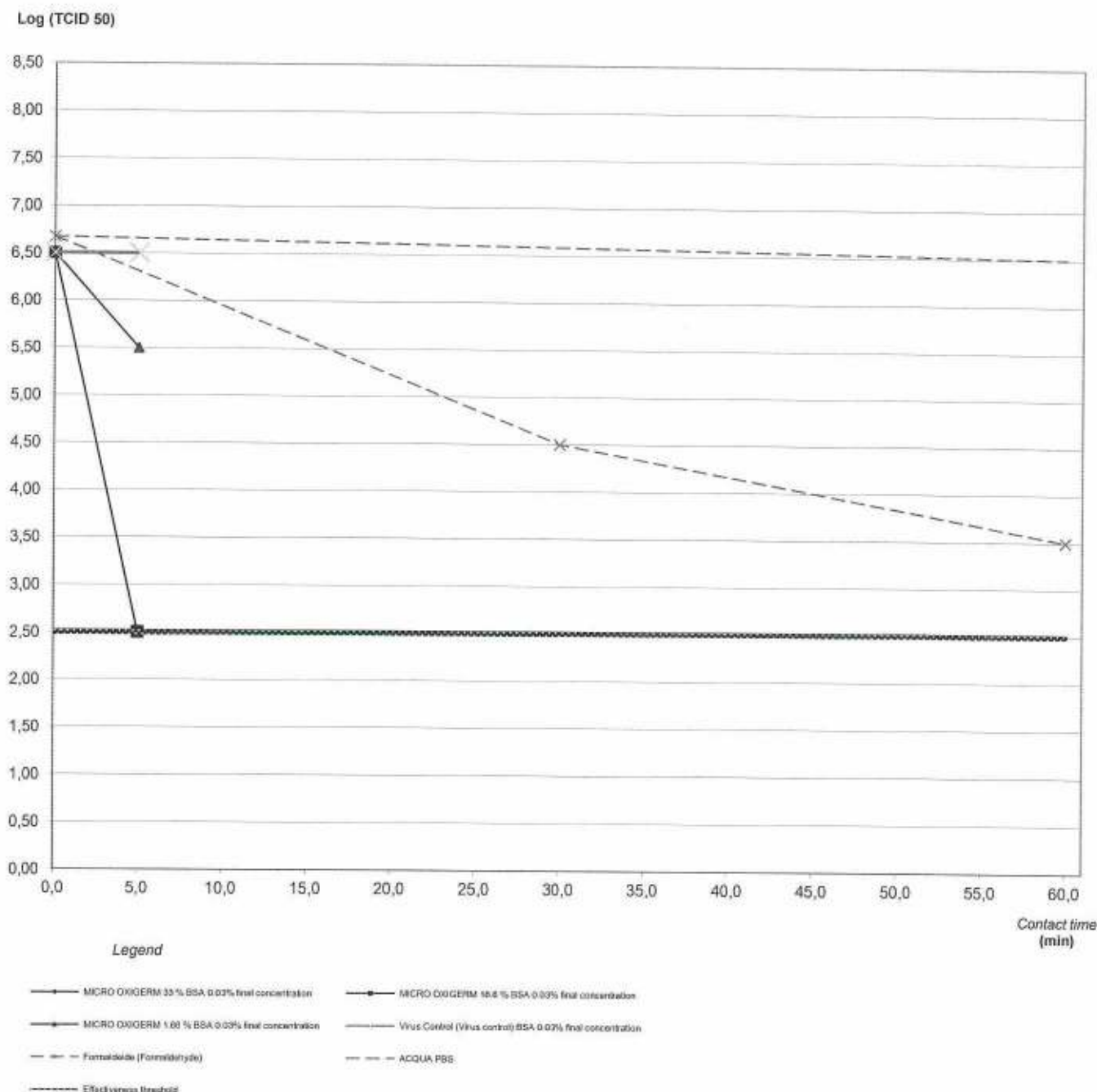
	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 11 / 38
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Presentazione grafica del saggio (Graphic presentation of test)**Poliovirus Type 1 LSc-2ab**

Data verifica Approver (Approver verification date): 25/05/20

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Revision: 1

Local reference: Mod. PS/MIC/112.E

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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 12 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità (Cytotoxicity)
Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26-05-20Sigla Approver e data (Approver signature and date): OC 26/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 13 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità dopo filtrazione (Cytotoxicity after filtration)
Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% Hela ATCC CCL-2 BSA 0.03% final concentration	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
	F	0	0	0	0	0	0	0	0	0	0
	G	0	0	0	0	0	0	0	0	0	0
	Endpoint	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
Log TCID50: **0,50**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Ma 26.05.20Sigla Approver e data (Approver signature and date): De 26/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 14 / 33
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Adenovirus Type 5 ATCC VR-5**Titolazione virus (Virus Titration)**

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Adenovirus Type 5 ATCC VR-5	B	0	4	4	4	3	3	2	1	0	0
	C	0	4	4	4	3	3	2	1	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	2	1	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	1	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	66,7	0,0	0,0

Cell destruction:

VALID

Log TCID50: 7,17 ± 0,400

Titolazione virale dopo filtrazione (Virus Titration after filtration)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Adenovirus Type 5 ATCC VR-5	B	0	4	4	4	4	3	2	0	0	0
	C	0	4	4	4	4	3	2	2	0	0
	D	0	4	4	4	4	3	2	0	0	0
	E	0	4	4	4	4	3	2	2	0	0
	F	0	4	4	4	4	3	2	2	0	0
	G	0	4	4	4	4	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0

Cell destruction:

VALID

Log TCID50: 7,00 ± 0,447

Reduction: 0,17 VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26.5.20

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Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 15 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo sensibilità al virus (Control of virus sensitivity)

Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
PBS	B	0	4	4	4	4	3	2	1	0	0
	C	0	4	4	4	4	3	2	1	0	0
	D	0	4	4	4	4	3	2	1	0	0
	E	0	4	4	4	4	3	2	1	0	0
	F	0	4	4	4	4	3	2	1	0	0
	G	0	4	4	4	4	3	2	1	0	0
	60 min	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0

Cell destruction:

VALID

Log TCID50: 7,50 ± 0,000

Condizioni testate (Test condition)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 60 min	B	0	4	4	4	4	3	2	0	0	0
	C	0	4	4	4	4	3	2	1	0	0
	D	0	4	4	4	4	3	2	1	0	0
	E	0	4	4	4	4	3	2	1	0	0
	F	0	4	4	4	4	3	2	0	0	0
	G	0	4	4	4	4	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0

Cell destruction:

VALID

Log TCID50: 7,00 ± 0,447

Reduction: 0,50 VALID

Condizioni testate (Test condition)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 60 min	B	0	4	4	4	4	3	2	0	0	0
	C	0	4	4	4	4	3	2	1	0	0
	D	0	4	4	4	4	3	2	1	0	0
	E	0	4	4	4	4	3	2	1	0	0
	F	0	4	4	4	4	3	2	1	0	0
	G	0	4	4	4	4	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	66,7	0,0	0,0

Cell destruction:

VALID

Log TCID50: 7,17 ± 0,400

Reduction: 0,33 VALID

Condizioni testate (Test condition)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 60 min	B	0	4	4	4	4	3	2	1	0	0
	C	0	4	4	4	4	3	2	1	0	0
	D	0	4	4	4	4	3	2	1	0	0
	E	0	4	4	4	4	3	2	1	0	0
	F	0	4	4	4	4	3	2	1	0	0
	G	0	4	4	4	4	3	2	1	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0

Cell destruction:

VALID

Log TCID50: 7,50 ± 0,000

Reduction: 0,00 VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mh 26.05.20

Sigla Approver e data (Approver signature and date): Gc 23/05/20

	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 16 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)
 Citotossicità riferimento (Reference Cytotoxicity)
 Hela ATCC CCL-2

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
Formaldeide (Formaldehyde) 0,7% PBS	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
Cell destruction: VALID											
Log TCID50: 2.50											

 Virus Control (Virus control)
 Hela ATCC CCL-2
 Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 0 min	B	0	4	4	3	3	2	1	0	0	0
	C	0	4	4	3	3	2	1	0	0	0
	D	0	4	4	3	3	2	0	0	0	0
	E	0	4	4	3	3	2	1	0	0	0
	F	0	4	4	3	3	2	1	0	0	0
	G	0	4	4	3	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	66,7	0,0	0,0	0,0
Cell destruction: VALID											
Log TCID50: 7,17 ± 0,400											

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 60 min	B	0	4	4	3	3	1	0	0	0	0
	C	0	4	4	3	3	1	0	0	0	0
	D	0	4	4	3	3	1	1	0	0	0
	E	0	4	4	3	3	1	1	0	0	0
	F	0	4	4	3	3	1	1	0	0	0
	G	0	4	4	3	3	1	1	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	66,7	0,0	0,0	0,0
Cell destruction: VALID											
Log TCID50: 7,17 ± 0.400											

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mh 26.05/20Sigla Approver e data (Approver signature and date): JP 23/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica	Pagina (Page) 17 / 33
	(Quantitative suspension test for the evaluation of virucidal activity in the medical area)	EDR: 1-P-QM-TEM-9081579
Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019		

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)

Hela ATCC CCL-2

Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 30 min	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	2	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	2	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	33,3	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

3,83

±

0,400

Reduction:

3,34

±

0,283

PASS

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 60 min	B	0	4	3	0	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	0	0	0	0	0	0	0
	E	0	4	3	0	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

3,50

±

0,000

Reduction:

3,67

±

0,200

PASS

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mh 26/5/20Sigla Approver e data (Approver signature and date): OM 28/5/20

	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 18 / 33
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Virus Control (Virus control)
Hela ATCC CCL-2
Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration 0 min	B	0	4	4	3	3	2	1	0	0	0
	C	0	4	4	3	3	2	1	0	0	0
	D	0	4	4	3	3	2	1	0	0	0
	E	0	4	4	3	3	2	1	0	0	0
	F	0	4	4	3	3	2	1	0	0	0
	G	0	4	4	3	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	83,3	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: **7,33 ± 0,346**

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration Maximum contact time tested	B	0	4	4	3	3	2	0	0	0	0
	C	0	4	4	3	3	2	1	0	0	0
	D	0	4	4	3	3	2	0	0	0	0
	E	0	4	4	3	3	2	1	0	0	0
	F	0	4	4	3	3	2	1	0	0	0
	G	0	4	4	3	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: **7,00 ± 0,447**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): M 26.05.20Sigla Approver e data (Approver signature and date): AT 28/05/20

Revision: 1	Local reference: Mod. PS/MIC/112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 19 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo soppressione attività prodotto (Control of suppression of product's activity)

Hela ATCC CCL-2

Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	1	0	0	0	0
	C	0	4	4	3	2	1	0	0	0	0
	D	0	4	4	3	2	1	0	0	0	0
	E	0	4	4	3	2	1	0	0	0	0
	F	0	4	4	3	2	1	0	0	0	0
	G	0	4	4	3	2	1	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: **6,50** ± **0,000**
 Reduction: **0,50** **VALID**

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	1	0	0	0	0
	C	0	4	4	3	2	1	0	0	0	0
	D	0	4	4	3	2	1	0	0	0	0
	E	0	4	4	3	2	1	0	0	0	0
	F	0	4	4	3	2	1	0	0	0	0
	G	0	4	4	3	2	1	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: **6,50** ± **0,000**
 Reduction: **0,50** **VALID**

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	1	0	0	0	0
	C	0	4	4	3	2	1	0	0	0	0
	D	0	4	4	3	2	1	0	0	0	0
	E	0	4	4	3	2	1	0	0	0	0
	F	0	4	4	3	2	1	0	0	0	0
	G	0	4	4	3	2	1	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: **6,50** ± **0,000**
 Reduction: **0,50** **VALID**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mh 26/05/20Sigla Approver e data (Approver signature and date): De 26/05/20

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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 20 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Procedura test (Test procedure)
 Hela ATCC CCL-2
 Adenovirus Type 5 ATCC VR-5

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: 2,50 ± 0,000
 Log reduction: 4,50 ± 0,224

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: 2,50 ± 0,000
 Log reduction: 4,50 ± 0,224

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 5 min	B	0	4	4	2	0	0	0	0	0	0
	C	0	4	4	2	0	0	0	0	0	0
	D	0	4	4	2	0	0	0	0	0	0
	E	0	4	4	2	0	0	0	0	0	0
	F	0	4	4	2	0	0	0	0	0	0
	G	0	4	4	2	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction: **VALID**
 Log TCID50: 4,50 ± 0,000
 Log reduction: 2,50 ± 0,224

Data verifica Approver (Approver verification date): 25/05/20

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 eurofins	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 21 / 33
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Result summary**Attività virucida (Virucidal activity)**
Adenovirus Type 5 ATCC VR-5

Prodotto (Product)	MICRO OXIGERM	
Sostanza interferente (Interfering substance)	BSA 0.03% final concentration	
Tempo di contatto (Contact time)	5 min	
Concentrazione (Concentration)	Riduzione Log (Log Reduction)	Status
33,0%	4.5 ± 0.22	PASS
16,6%	4.5 ± 0.22	PASS
1,66%	2.5 ± 0.22	FAIL

Data verifica Approver (Approver verification date): 25/05/20

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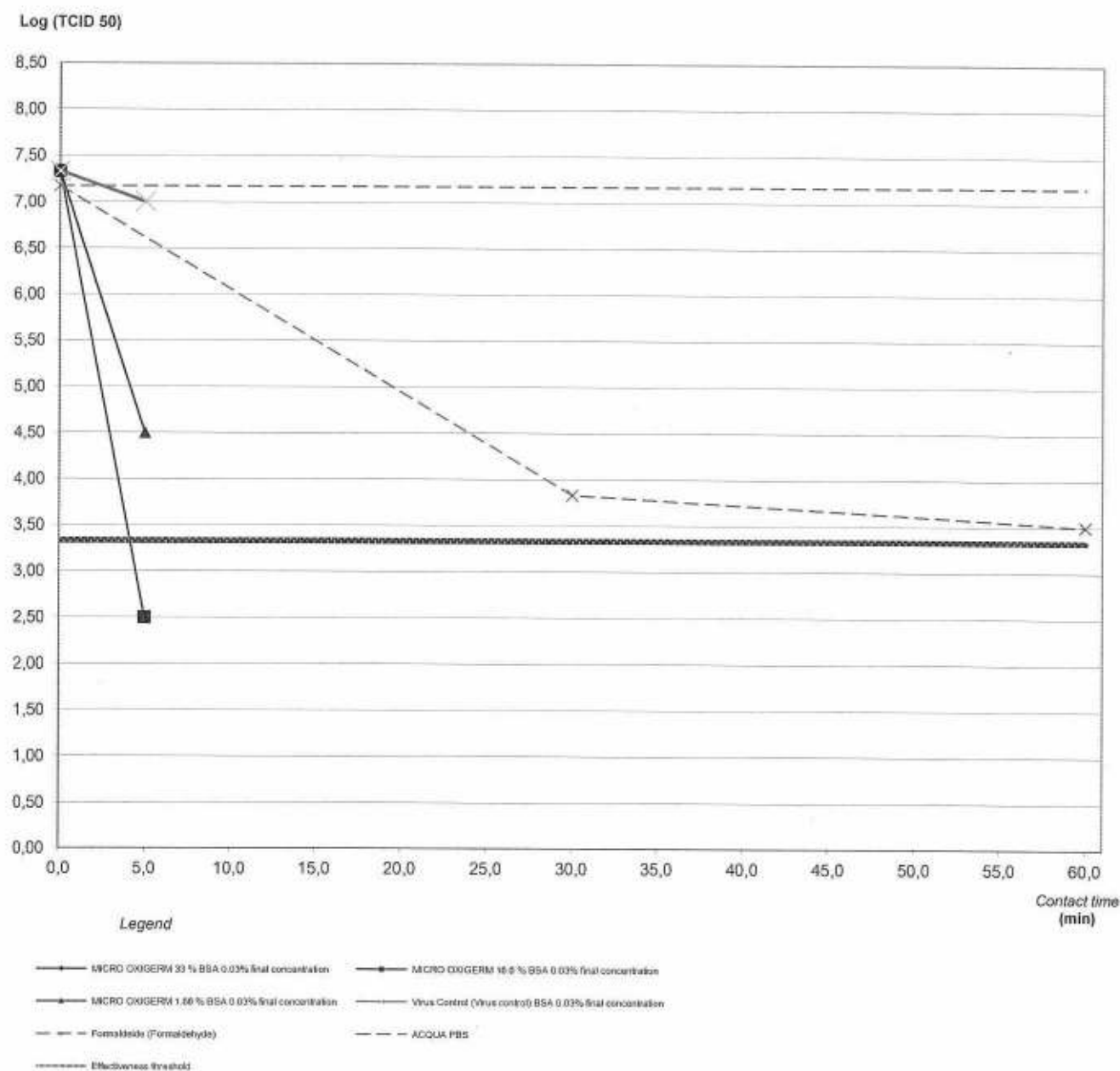
	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 22 / 33
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 18/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Presentazione grafica del saggio (Graphic presentation of test)**Adenovirus Type 5 ATCC VR-5**

Data verifica Approver (Approver verification date): 25/05/20

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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 23 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità (Cytotoxicity)
RAW 264.7 ATCC TIB-71

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	4	4	0	0	0	0	0	0	0
	C	0	4	4	0	0	0	0	0	0	0
	D	0	4	4	0	0	0	0	0	0	0
	E	0	4	4	0	0	0	0	0	0	0
	F	0	4	4	0	0	0	0	0	0	0
	G	0	4	4	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	4	4	0	0	0	0	0	0	0
	C	0	4	4	0	0	0	0	0	0	0
	D	0	4	4	0	0	0	0	0	0	0
	E	0	4	4	0	0	0	0	0	0	0
	F	0	4	4	0	0	0	0	0	0	0
	G	0	4	4	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Data verifica Approver (Approver verification date): 25/05/20

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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 24 / 33
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Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Citotossicità dopo filtrazione (Cytotoxicity after filtration)
RAW 264.7 ATCC TIB-71

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 33,0% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 16,6% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **1,50**

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM 1,66% RAW 264.7 ATCC TIB-71 BSA 0.03% final concentration	B	0	0	0	0	0	0	0	0	0	0
	C	0	0	0	0	0	0	0	0	0	0
	D	0	0	0	0	0	0	0	0	0	0
	E	0	0	0	0	0	0	0	0	0	0
	F	0	0	0	0	0	0	0	0	0	0
	G	0	0	0	0	0	0	0	0	0	0
	Endpoint	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **0,50**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26.05.6Sigla Approver e data (Approver signature and date): Be 28.05.20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 25 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Murine norovirus (MNV, strain S99) RVB-651

Titolazione virus (Virus Titration)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Murine norovirus (MNV, strain S99) RVB-651	B	0	4	4	4	3	3	2	0	0	0
	C	0	4	4	4	3	3	2	0	0	0
	D	0	4	4	4	3	3	2	0	0	0
	E	0	4	4	4	3	3	2	0	0	0
	F	0	4	4	4	3	3	2	0	0	0
	G	0	4	4	4	3	3	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50: 6,50 ± 0,000

Titolazione virale dopo filtrazione (Virus Titration after filtration)

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
Murine norovirus (MNV, strain S99) RVB-651	B	0	4	4	4	3	2	2	0	0	0
	C	0	4	4	4	3	2	2	0	0	0
	D	0	4	4	4	3	2	2	0	0	0
	E	0	4	4	4	3	2	2	0	0	0
	F	0	4	4	4	3	2	2	0	0	0
	G	0	4	4	4	3	2	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50: 6,50 ± 0,000

Reduction: 0,00 VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mh 26.05.20Sigla Approver e data (Approver signature and date): De 28/05/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 26 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo sensibilità al virus (Control of virus sensitivity)

Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
PBS	B	0	4	4	3	3	2	2	0	0	0
	C	0	4	4	3	3	2	2	0	0	0
	D	0	4	4	3	3	2	2	0	0	0
	E	0	4	4	3	3	2	2	0	0	0
	F	0	4	4	3	3	2	2	0	0	0
	G	0	4	4	3	3	2	2	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0
60 min											

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	3	3	2	0	0	0	0
	C	0	4	4	3	3	2	0	0	0	0
	D	0	4	4	3	3	2	1	0	0	0
	E	0	4	4	3	3	2	1	0	0	0
	F	0	4	4	3	3	2	0	0	0	0
	G	0	4	4	3	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	33,3	0,0	0,0	0,0
33,0% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50:

5,83

±

0,400

Reduction:

0,67

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	3	3	2	0	0	0	0
	C	0	4	4	3	3	2	0	0	0	0
	D	0	4	4	3	3	2	0	0	0	0
	E	0	4	4	3	3	2	1	0	0	0
	F	0	4	4	3	3	2	1	0	0	0
	G	0	4	4	3	3	2	1	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0	0,0
16,6% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50:

6,00

±

0,447

Reduction:

0,50

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			1	2	3	4	5	6	7	8	
MICRO OXIGERM	B	0	4	4	3	3	2	1	0	0	0
	C	0	4	4	3	3	2	1	0	0	0
	D	0	4	4	3	3	2	1	0	0	0
	E	0	4	4	3	3	2	0	0	0	0
	F	0	4	4	3	3	2	0	0	0	0
	G	0	4	4	3	3	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0	0,0
1,66% BSA 0.03% final concentration 60 min											

Cell destruction:

VALID

Log TCID50:

6,00

±

0,447

Reduction:

0,50

VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MA 26.05.20Sigla Approver e data (Approver signature and date): DE 26.05.20

	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 27 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)
Citotossicità riferimento (Reference Cytotoxicity)
RAW 264.7 ATCC TIB-71

Condizioni testate (Test condition)	Replica	K-	Diluizione sostanza in esame (Test item dilution)								K-
			1	2	3	4	5	6	7	8	
Formaldeide (Formaldehyde) 0,7% PBS	B	0	4	4	0	0	0	0	0	0	0
	C	0	4	4	0	0	0	0	0	0	0
	D	0	4	4	0	0	0	0	0	0	0
	E	0	4	4	0	0	0	0	0	0	0
	F	0	4	4	0	0	0	0	0	0	0
	G	0	4	4	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **2,50**
Virus Control (Virus control)
RAW 264.7 ATCC TIB-71
Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 0 min	B	0	4	4	4	4	2	0	0	0	0
	C	0	4	4	4	4	2	0	0	0	0
	D	0	4	4	4	4	2	0	0	0	0
	E	0	4	4	4	4	2	0	0	0	0
	F	0	4	4	4	4	2	0	0	0	0
	G	0	4	4	4	4	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **6,50 ± 0,000**

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) PBS 60 min	B	0	4	4	4	3	1	0	0	0	0
	C	0	4	4	4	3	0	0	0	0	0
	D	0	4	4	4	3	0	0	0	0	0
	E	0	4	4	4	3	1	0	0	0	0
	F	0	4	4	4	3	1	0	0	0	0
	G	0	4	4	4	3	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	50,0	0,0	0,0	0,0	0,0

 Cell destruction: **VALID**
 Log TCID50: **6,00 ± 0,447**

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): M 26.05.20Sigla Approver e data (Approver signature and date): Dr 26/5/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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 eurofins	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 28 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Test di riferimento per l'inattivazione del virus (Reference test for virus inactivation)

RAW 264.7 ATCC TIB-71

Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 30 min	B	0	4	4	2	0	0	0	0	0	0
	C	0	4	4	2	0	0	0	0	0	0
	D	0	4	4	2	0	0	0	0	0	0
	E	0	4	4	2	0	0	0	0	0	0
	F	0	4	4	2	0	0	0	0	0	0
	G	0	4	4	2	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

4,50

± 0,000

Reduction:

1,50

±

0,000

PASS

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
Formaldeide (Formaldehyde) 0,7% PBS 60 min	B	0	4	4	0	0	0	0	0	0	0
	C	0	4	4	0	0	0	0	0	0	0
	D	0	4	4	0	0	0	0	0	0	0
	E	0	4	4	0	0	0	0	0	0	0
	F	0	4	4	0	0	0	0	0	0	0
	G	0	4	4	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

3,50

± 0,000

Reduction:

2,50

±

0,000

PASS

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MA 16.05.20Sigla Approver e data (Approver signature and date): Be 23/05/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 29 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Virus Control (Virus control)

RAW 264.7 ATCC TIB-71

Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration 0 min	B	0	4	4	4	4	3	0	0	0	0
	C	0	4	4	4	4	3	0	0	0	0
	D	0	4	4	4	4	3	0	0	0	0
	E	0	4	4	4	4	3	0	0	0	0
	F	0	4	4	4	4	3	0	0	0	0
	G	0	4	4	4	4	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
ACQUA (WATER) BSA 0.03% final concentration Maximum contact time tested	B	0	4	4	4	4	3	0	0	0	0
	C	0	4	4	4	4	3	0	0	0	0
	D	0	4	4	4	4	3	0	0	0	0
	E	0	4	4	4	4	3	0	0	0	0
	F	0	4	4	4	4	3	0	0	0	0
	G	0	4	4	4	4	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mm 16-05/20Sigla Approver e data (Approver signature and date): Se 23/05/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica (Quantitative suspension test for the evaluation of virucidal activity in the medical area) Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 30 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Controllo soppressione attività prodotto (Control of suppression of product's activity)

RAW 264.7 ATCC TIB-71

Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)							K-	
			2	3	4	5	6	7	8		9
MICRO OXIGERM 33,0% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	2	0	0	0	0
	C	0	4	4	3	2	2	0	0	0	0
	D	0	4	4	3	2	2	0	0	0	0
	E	0	4	4	3	2	0	0	0	0	0
	F	0	4	4	3	2	2	0	0	0	0
	G	0	4	4	3	2	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	83,3	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,33

±

0,346

Reduction:

0,17

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)							K-	
			2	3	4	5	6	7	8		9
MICRO OXIGERM 16,6% BSA 0.03% final concentration 0 min	B	0	4	4	3	2	0	0	0	0	0
	C	0	4	4	3	2	2	0	0	0	0
	D	0	4	4	3	2	2	0	0	0	0
	E	0	4	4	3	2	2	0	0	0	0
	F	0	4	4	3	2	2	0	0	0	0
	G	0	4	4	3	2	2	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	83,3	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,33

±

0,346

Reduction:

0,17

VALID

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)							K-	
			2	3	4	5	6	7	8		9
MICRO OXIGERM 1,66% BSA 0.03% final concentration 0 min	B	0	4	4	3	3	3	0	0	0	0
	C	0	4	4	3	3	3	0	0	0	0
	D	0	4	4	3	3	3	0	0	0	0
	E	0	4	4	3	3	3	0	0	0	0
	F	0	4	4	3	3	3	0	0	0	0
	G	0	4	4	3	3	3	0	0	0	0
	Endpoint	0,0	100,0	100,0	100,0	100,0	100,0	0,0	0,0	0,0	0,0

Cell destruction:

VALID

Log TCID50:

6,50

±

0,000

Reduction:

0,00

VALID

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): Mu 26.05.20Sigla Approver e data (Approver signature and date): Gr 23.05.20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 31 / 33 EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Procedura test (Test procedure)

RAW 264.7 ATCC TIB-71

Murine norovirus (MNV, strain S99) RVB-651

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 33,0% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
			Cell destruction: VALID Log TCID50: 2,50 ± 0,000 Log reduction: 4,00 ± 0,000								

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 16,6% BSA 0.03% final concentration 5 min	B	0	4	0	0	0	0	0	0	0	0
	C	0	4	0	0	0	0	0	0	0	0
	D	0	4	0	0	0	0	0	0	0	0
	E	0	4	0	0	0	0	0	0	0	0
	F	0	4	0	0	0	0	0	0	0	0
	G	0	4	0	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
			Cell destruction: VALID Log TCID50: 2,50 ± 0,000 Log reduction: 4,00 ± 0,000								

Condizioni testate (Test condition)	Replica	K-	Diluizione virus (Virus dilution)								K-
			2	3	4	5	6	7	8	9	
MICRO OXIGERM 1,66% BSA 0.03% final concentration 5 min	B	0	4	3	2	0	0	0	0	0	0
	C	0	4	3	0	0	0	0	0	0	0
	D	0	4	3	2	0	0	0	0	0	0
	E	0	4	3	2	0	0	0	0	0	0
	F	0	4	3	0	0	0	0	0	0	0
	G	0	4	3	0	0	0	0	0	0	0
	Endpoint	0,0	100,0	100,0	50,0	0,0	0,0	0,0	0,0	0,0	0,0
			Cell destruction: VALID Log TCID50: 4,00 ± 0,447 Log reduction: 2,50 ± 0,224								

Data verifica Approver (Approver verification date): 25/05/20

Sigla Tecnico e data (Technician signature and date): MM 26/5/20Sigla Approver e data (Approver signature and date): AE 25/5/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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 eurofins	Prova quantitativa in sospensione per la valutazione dell'attività virucida in area medica <i>(Quantitative suspension test for the evaluation of virucidal activity in the medical area)</i> Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	Pagina (Page) 32 / 33
		EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Result summary**Attività virucida (Virucidal activity)****Murine norovirus (MNV, strain S99) RVB-651**

Prodotto (Product)	MICRO OXIGERM	
Sostanza interferente (Interfering substance)	BSA 0.03% final concentration	
Tempo di contatto (Contact time)	5 min	
Concentrazione (Concentration)	Riduzione Log (Log Reduction)	Status
33,0%	4 ± 0	PASS
16,6%	4 ± 0	PASS
1,66%	2.5 ± 0.22	FAIL

Data verifica Approver (Approver verification date): 25/05/20

Sigla Approver e data (Approver signature and date): GE 25/05/20

Revision: 1	Local reference: Mod. PS/MIC/0112.E
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	Norma (Standard): EN14476:2013+A2:2019 / UNI EN 14476:2019	EDR: 1-P-QM-TEM-9081579

Data inizio (Started on): 12/05/20

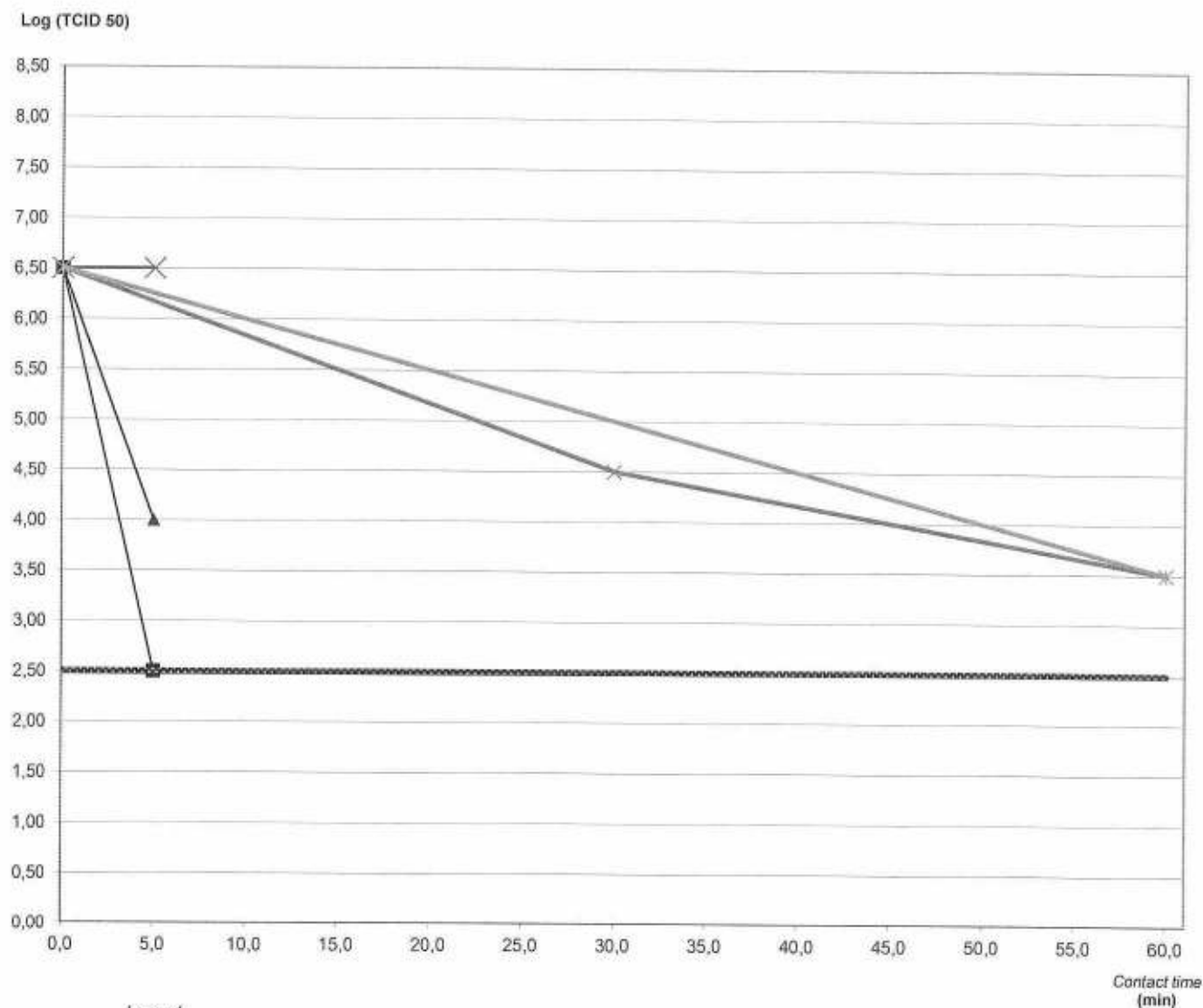
Data fine sperimentazione (Experimentation finished on): 15/05/20

Rapporto No (Report No): STULV20AA2201-1

ID Campione (ID sample): LV-MAT-FOV7-20-119-0919:a

Presentazione grafica del saggio (Graphic presentation of test)

Murine norovirus (MNV, strain S99) RVB-651



Data verifica Approver (Approver verification date): 25/05/20

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