a) **Identification of test laboratory:**

Test laboratory	MGS Laboratories Ltd Unit 14, Newlands Drive Poyle 14 Horton Road Poyle Berkshire SL3 0DX

b) **Identification of the Customer:**

Customer Name	Goldshield Industries (Europe) Ltd
Customer Address	2 Victoria Square Victoria Street St Albans AL1 3TF

c) **Identification of the sample:**

Name of product	Goldshield 75
Batch number (and expiry date if available)	BN001
Manufacturer (or supplier)	Goldshield Industries (Europe) Ltd
Date of delivery	23 May 12
Storage conditions	Room temperature and darkness
Product diluent recommended by the manufacturer for use	Not stated
Active substance(s) and their concentration(s) (optional)	Not stated
Appearance of the product	White cloudy solution

d) **Test method and its validation:**

MGS procedure reference	WIN-1000.050-05
Method	Dilution neutralisation Membrane filtration
Neutraliser	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Rinsing liquid	Sterile Distilled Water
Details of validation of the neutraliser	Neutraliser validation performed according to 5.5.2 of EN 1276:2009; a valid neutraliser could not be determined against

Staphylococcus aureus therefore membrane filtration was used.

e) **Experimental conditions:**

Period of analysis	24 May 12 – 12 Jun 12
Product diluent used during the test	Ready to use product
Product test concentrations	Ready to Use (RTU)
Appearance of product dilutions	White cloudy solution
Contact time	5 minutes ± 10s
Test temperature range	20°C ± 2°C
Interfering substance	3.0g/l Bovine albumin
Stability of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C ± 2°C
Identification of the bacterial strains used	*Escherichia coli* NCTC 10418 *Enterococcus hirae* NCIMB 8192 *Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442

f) **Results:**

Test results	1) Controls and validation 2) Evaluation of bactericidal activity
g) **Conclusion:**	Based on EN 1276 (2009), the batch BN001 of the product Goldshield 75 when tested at RTU, possesses bactericidal activity in 5 minutes at 20°C under dirty conditions for the referenced strains of *E. coli*, *E. hirae*, *S. aureus* and *P. aeruginosa*.
h) **Deviations:**	None All controls and validations were within basic limits No precipitate was formed during the test.
i) Special remarks	The *Pseudomonas aeruginosa* result narrowly failed to meet the acceptance criteria; since difference between this result and the acceptance criteria was within MGS's standard uncertainty the testing was repeated in duplicate. The mean of the three results meets the acceptance criteria.

Prepared By: [signature]

Name: Miss Claire Crawshaw MBiomedSci

Position: Laboratory Manager

Date: 21 JUN 12

Approved by: [signature]

Name: Mrs Emma Newton BSc (Hons)

Position: Quality Manager

Date: 21 Jun 12

The MGS procedure WIN-1000.050 is a laboratory method based on the EN 1276 (2009) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- EN 1276 states an allowed tolerance of 36°C ±1°C or 37°C±1°C, MGS laboratories equipment is validated to ±2°C therefore MGS procedures state ±2°C. The tests are self validating so any stress caused to the organism will be reflected in the validations.
- A cryovial bead is added to broth and stored at 2-8°C for a maximum of 7 days; streaks are made from these broths, rather than streaking from stored slopes for 6-9 weeks.
- Organisms are prepared by swabbing plates and adding to 9ml diluent to form a suspension, rather than adding loopfuls of organism to 10ml diluent with beads, shaking for 3 minutes, aspirating and adding to a new container. Swabbing forms a smooth suspension removing the need to shake with beads.
- The laboratory is regulated at 20°C; therefore for testing at 20°C a water bath is not used.
- Plates are incubated for the full time rather than performing an interim read; in addition the incubation period may be extended to a maximum of 4 due to business hours
- All tests performed include validation of neutralisation, but the neutraliser is not always pre-proved.
- Neutraliser is prepared at 8ml and 9ml taking into account required concentrations so that water does not have to be added to 8ml for Test and NTV aliquots.
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism

Product batch number: BN001
Dilution-neutralisation method Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.3°C
Test organism: *P. aeruginosa* ATCC 15442 (Replicate 1)
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 24 May 12
Person responsible: Radoslaw Maczko Signature: Radoslaw Maczko
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	23	χ = 30	Vc1	39	χ = 37	Vc1	54	χ = 45	Vc1	43	χ = 40
Vc2	36		Vc2	35		Vc2	36		Vc2	36	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ = 46 x 10^7; lgN = 8.66
	10^{-6}	>330	>330	N_0 = N/10; lgN_0 = 7.66
	10^{-7}	46	46	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	59	56	580	2.76	4.90	5 min

Product batch number: BN001
Dilution-neutralisation method Pour plate [X] Spread plate
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 19.3°C
Test organism: *P. aeruginosa* ATCC 15442 (Replicate 2)
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 14 Jun 12
Person responsible: Mathew Furtado Signature: MFurtado
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	67	χ = 58	Vc1	51	χ = 54	Vc1	45	χ = 68	Vc1	87	χ = 87
Vc2	48		Vc2	57		Vc2	90		Vc2	86	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 175 x 10^6; lgN = 8.24
	10^{-6}	172	189	N_0 = N/10; lgN_0 = 7.24
	10^{-7}	16	7	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	<14	<14	<140	<2.15	>5.09	5 min

Product batch number: BN001
Dilution-neutralisation method Pour plate [X] Spread plate
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 19.3°C
Test organism: *P. aeruginosa* ATCC 15442 (Replicate 3)
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 14 Jun 12
Person responsible: Mathew Furtado Signature: MFurtado
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	52	χ = 52	Vc1	35	χ = 31	Vc1	43	χ = 40	Vc1	89	χ = 85
Vc2	52		Vc2	27		Vc2	37		Vc2	90	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 205 x 10^6; lgN = 8.31
	10^{-6}	198	210	N_0 = N/10; lgN_0 = 7.31
	10^{-7}	16	26	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	<14	<14	<140	<2.15	>5.16	5 min

Replicate of *P.aeruginosa*	**Log Reduction**	**Mean Log Reduction**
1	4.90	>5.05
2	>5.09	
3	>5.16	

Product batch number: BN001
Dilution-neutralisation method Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.4°C
Test organism: *E. coli* NCTC 10418
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 01 Jun 12
Person responsible: Charlotte Priestman Signature: Priestman
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	66	χ = 57	Vc1	52	χ = 52	Vc1	50	χ = 54	Vc1	40	χ = 43
Vc2	48		Vc2	52		Vc2	58		Vc2	45	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 213 x 10^6; lgN= 8.33
	10^{-6}	214	214	N_0 = N/10; lgN_0 = 7.33.
	10^{-7}	26	15	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	<14	<14	<140	<2.15	>5.18	5 min

Product batch number: BN001
Membrane filtration method
Number of plates: 1 / ml
Rinsing liquid: Sterile distilled water
Actual test temperature: 19.8°C
Test organism: *S. aureus* ATCC 6538
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 06 Jun 12
Person responsible: Radoslaw Maczko Signature: Radoslaw Maczko
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Filtration Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	54	χ = 50	Vc1	43	χ = 45	Vc1	32	χ = 46	Vc1	24	χ = 28
Vc2	46		Vc2	46		Vc2	59		Vc2	31	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 238 x 10^6; lgN= 8.38
	10^{-6}	238	228	N_0 = N/10; lgN_0 = 7.38
	10^{-7}	29	28	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	<14	<14	<140	<2.15	>5.23	5 min

Product batch number: BN001
Dilution-neutralisation method Pour plate [X] Spread plate [ ]
Number of plates: 1 / ml
Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l
Actual test temperature: 20.4°C
Test organism: *E. hirae* NCIMB 8192
Incubation temperature: 36°C ± 2°C
Interfering substances: 3.0g/l Bovine albumin
Date of Test: 01 Jun 12
Person responsible: Charlotte Priestman Signature: Priestman
Diluent used for product test solutions: Sterile water
Appearance of product test solutions: White cloudy solution

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	64	χ = 71	Vc1	66	χ = 71	Vc1	84	χ = 75	Vc1	84	χ = 74
Vc2	77		Vc2	76		Vc2	65		Vc2	64	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 265 x 10^6; lgN= 8.42
	10^{-6}	245	258	N_0 = N/10; lgN_0 = 7.42
	10^{-7}	49	30	7.17 ≤ lg N_0 ≤ 7.70? Yes [X] No [ ]

Conc of the product	**Vc1**	**Vc2**	**Na = χ x10**	**lgNa**	**lgR**	**Contact time**
RTU	<14	<14	>140	<2.15	>5.27	5 min

Explanations:
Vc = count per plate (one plate or more)
χ = average of Vc1 and Vc2 (1. + 2. duplicate)
χ wm = weighed mean of χ
R = reduction ($lgR = lgN_0 - lgNa$)
Na = number of survivors in the test mixture
N = number of cells in the test suspension
N_0 =N/10
Nv = number of cells in the validation suspension
Nv_0 = Nv/10

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.