

Company Name: Zimpli Medical Ltd

Contact Name: Eejay Enyi

Contact Email: eejay@zimplikids.com

Purchase Order No: NA

Report Date: 13/04/2020

**Melbec Ref Number:** 16204

**No. of Samples:** 1

**Name of Test Product:** Hand Sanitiser

**Batch Number:** BSD01042020-01

**Sample Details:**

Manufacture / Supplier:..... Zimpli Medical Ltd  
Product storage conditions:..... Ambient  
Appearance of the product (as supplied):..... Clear liquid  
Appearance of the product (after dilution):..... N/A  
Appearance of product with interfering substance and test organism: Clear liquid  
Active substance and concentration:..... Propan-2-ol  
Product dilutions/concentrations:..... Ready to Use (RTU)  
Diluent used to dilute product:..... Sterile Deionised Water

Incubation temperature: ..... 36 degrees

The test product was in satisfactory condition for testing when received.

Date product received: 09/04/20 Test Date: 11/04/20

**Experimental Conditions:**

Interfering substance: Bovine Albumin (clean 0.3g/l)  
Test temperature: 18 to 25 °C  
Contact time: 30 Seconds  
Test organisms: Pseudomonas aeruginosa ATCC 15442  
Staphylococcus aureus ATCC 6538  
Escherichia coli K12 NCTC 10538  
Enterococcus hirae ATCC 10541

**Requirements of the Standard:**

The test product shall demonstrate at least a 5 decimal logarithm (lg) reduction when tested in accordance with this standard under simulated clean or dirty conditions.

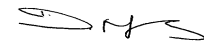
**Conclusion:**

For the product Hand Sanitiser, [BSD01042020-01] the log reduction requirements as specified in EN 1276:2019 (5 lg within the relevant contact time) were met.

Testing carried out by:

Name: Danika Weatherburn  
Position: Laboratory Manager

Report authorised by:



Name: Dawn Mellors  
Position: Technical Director  
Date: 13/04/2020

**Test Results:**

**Neutralisation Method Used:**

Dilution neutralisation by pour plate

Neutraliser used                      N1

***Pseudomonas aeruginosa* ATCC  
15442**

| Validation and controls                                    |    |             |  |    |             |  |    |             | Melbec Ref No  | 16204 |             |
|--|----|-------------|--|----|-------------|--|----|-------------|--|-------|-------------|
| Validation suspension ( $Nv_0$ )                           |    |             | Experimental conditions control (A)  |    |             | Neutralizer control (B)  |    |             | Method validation (C)<br>Product conc: RTU   |       |             |
| Vc 1   | 69 | $\bar{X} =$ | Vc 1   | 39 | $\bar{X} =$ | Vc 1   | 54 | $\bar{X} =$ | Vc 1   | 35    | $\bar{X} =$ |
| Vc 2   | 63 | 66          | Vc 2   | 38 | 38.5        | Vc 2   | 51 | 52.5        | Vc 2   | 33    | 34          |
| $30 \leq \bar{X} \text{ of } Nv_0 \leq 160?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of A is } \geq 0.5 \times \bar{X} \text{ of } Nv_0?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of B is } \geq 0.5 \times \bar{X} \text{ of } Nv_0?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of C is } \geq 0.5 \times \bar{X} \text{ of } Nv_0?$<br><b>Yes</b> |       |             |

**Test suspension and test**

| Test suspension ( $N$ and $N_0$ ): | $N$       | Vc 1 | Vc 2 | $X_{wm}$ 2.62E+08 ; $\lg N =$ 8.42   |
|------------------------------------|-----------|------|------|--|
|                                    | $10^{-6}$ | 252  | 248  | $N_0 = N/10$ ; $\lg N_0 =$ 7.42  |
|                                    | $10^{-7}$ | 42   | 35   | $7.17 \leq \lg N_0 \leq 7.70?$ Yes<br>$\bar{X} \text{ quotient} = >5 \text{ and } <15?$ 6.49 |

| Conc. of the active (%) | Vc 1 | Vc 2 | $Na = \bar{X} \times 10$ | $\lg Na$ | $\lg R$<br>$N_0 =$ 7.42 | Contact time | Result      |
|-------------------------|------|------|--------------------------|----------|-------------------------|--------------|-------------|
| RTU                     | <14  | <14  | 1.40E+02                 | <2.15    | >5.27                   | 30 Seconds   | <b>Pass</b> |

**Staphylococcus aureus ATCC  
6538**

| Validation and controls                          |    |             |  |    |             |  |    |             | Melbec Ref No  | 16204 |             |
|--|----|-------------|--|----|-------------|--|----|-------------|--|-------|-------------|
| Validation suspension ( $N_{v_0}$ )              |    |             | Experimental conditions control (A)                              |    |             | Neutralizer control (B)  |    |             | Method validation (C)<br>Product conc: RTU                       |       |             |
| Vc 1   | 54 | $\bar{X} =$ | Vc 1   | 58 | $\bar{X} =$ | Vc 1   | 56 | $\bar{X} =$ | Vc 1   | 60    | $\bar{X} =$ |
| Vc 2   | 51 | 52.5        | Vc 2   | 39 | 48.5        | Vc 2   | 50 | 53          | Vc 2   | 57    | 58.5        |
| 30 ≤ $\bar{X}$ of $N_{v_0}$ ≤ 160?<br><b>Yes</b> |    |             | $\bar{X}$ of A is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |    |             | $\bar{X}$ of B is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |    |             | $\bar{X}$ of C is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |       |             |

**Test suspension and test**

|                                    | $N$       | Vc 1 | Vc 2 | $X_{wm}$ 2.13E+08 ; $\lg N =$ 8.33     |
|------------------------------------|-----------|------|------|--|
| Test suspension ( $N$ and $N_0$ ): | $10^{-6}$ | 214  | 214  | $N_0 = N/10$ ; $\lg N_0 =$ 7.33        |
|                                    | $10^{-7}$ | 24   | 17   | $7.17 \leq \lg N_0 \leq 7.70?$ Yes     |
|                                    |           |      |      | $\bar{X}$ quotient = >5 and <15? 10.44 |

| Conc. of the active (%) | Vc 1 | Vc 2 | $N_a = \bar{X} \times 10$ | $\lg N_a$ | $\lg R$<br>$N_0 =$ 7.33 | Contact time | Result      |
|-------------------------|------|------|---------------------------|-----------|-------------------------|--------------|-------------|
| RTU                     | <14  | <14  | 1.40E+02                  | <2.15     | >5.18                   | 30 Seconds   | <b>Pass</b> |

**Escherichia coli K12 NCTC  
10538**

| Validation and controls                                       |    |             |   |    |             |   |    |             | Melbec Ref No   | 16204 |             |
|---|----|-------------|---|----|-------------|---|----|-------------|---|-------|-------------|
| Validation suspension ( $N_{v_0}$ )                           |    |             | Experimental conditions control (A)   |    |             | Neutralizer control (B)   |    |             | Method validation (C)<br>Product conc: RTU  |       |             |
| Vc 1  | 71 | $\bar{X} =$ | Vc 1  | 66 | $\bar{X} =$ | Vc 1  | 65 | $\bar{X} =$ | Vc 1  | 53    | $\bar{X} =$ |
| Vc 2  | 71 | 71          | Vc 2  | 62 | 64          | Vc 2  | 60 | 62.5        | Vc 2  | 49    | 51          |
| $30 \leq \bar{X} \text{ of } N_{v_0} \leq 160?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of A is } \geq 0.5 \times \bar{X} \text{ of } N_{v_0}?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of B is } \geq 0.5 \times \bar{X} \text{ of } N_{v_0}?$<br><b>Yes</b> |    |             | $\bar{X} \text{ of C is } \geq 0.5 \times \bar{X} \text{ of } N_{v_0}?$<br><b>Yes</b> |       |             |

**Test suspension and test**

|                                 | N         | Vc 1 | Vc 2 | $X_{wm} \quad 2.18E+08 \quad ; \lg N = \quad 8.34$            |
|---------------------------------|-----------|------|------|---|
| Test suspension (N and $N_0$ ): | $10^{-6}$ | 220  | 217  | $N_0 = N/10 \quad ; \lg N_0 = \quad 7.34$                     |
|                                 | $10^{-7}$ | 24   | 19   | $7.17 \leq \lg N_0 \leq 7.70? \quad \text{Yes}$               |
|                                 |           |      |      | $\bar{X} \text{ quotient} = >5 \text{ and } <15? \quad 10.16$ |

| Conc. of the active (%) | Vc 1 | Vc 2 | $N_a = \bar{X} \times 10$ | $\lg N_a$ | $\lg R$<br>$N_0 = \quad 7.34$ | Contact time | Result      |
|-------------------------|------|------|---------------------------|-----------|-------------------------------|--------------|-------------|
| RTU                     | <14  | <14  | 1.40E+02                  | <2.15     | >5.19                         | 30 Seconds   | <b>Pass</b> |

**Enterococcus hirae ATCC 10541**

| Validation and controls                          |    |             |  |    |             |  |    |             | Melbec Ref No  | 16204 |             |
|--|----|-------------|--|----|-------------|--|----|-------------|--|-------|-------------|
| Validation suspension ( $N_{v_0}$ )              |    |             | Experimental conditions control (A)                              |    |             | Neutralizer control (B)  |    |             | Method validation (C)<br>Product conc: RTU                       |       |             |
| Vc 1   | 85 | $\bar{X} =$ | Vc 1   | 72 | $\bar{X} =$ | Vc 1   | 78 | $\bar{X} =$ | Vc 1   | 76    | $\bar{X} =$ |
| Vc 2   | 71 | 78          | Vc 2   | 67 | 69.5        | Vc 2   | 65 | 71.5        | Vc 2   | 74    | 75          |
| 30 ≤ $\bar{X}$ of $N_{v_0}$ ≤ 160?<br><b>Yes</b> |    |             | $\bar{X}$ of A is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |    |             | $\bar{X}$ of B is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |    |             | $\bar{X}$ of C is ≥ 0.5 x $\bar{X}$ of $N_{v_0}$ ?<br><b>Yes</b> |       |             |

**Test suspension and test**

|  |           |      |      |  |
|--|-----------|------|------|--|
| <b>Test suspension (N and <math>N_0</math>):</b> | <b>N</b>  | Vc 1 | Vc 2 | $X_{wm}$ 3.07E+08 ; $\lg N =$ 8.49   |
|  | $10^{-6}$ | >330 | 304  | $N_0 = N/10$ ; $\lg N_0 =$ 7.49  |
|  | $10^{-7}$ | 33   | 31   | 7.17 ≤ $\lg N_0$ ≤ 7.70? <b>Yes</b><br>$\bar{X}$ quotient = >5 and <15? 9.50 |

| Conc. of the active (%) | Vc 1 | Vc 2 | $N_a = \bar{X} \times 10$ | $\lg N_a$ | $N_0 =$ | <b>IgR</b><br>7.49 | Contact time | Result      |
|-------------------------|------|------|---------------------------|-----------|---------|--------------------|--------------|-------------|
| RTU                     | <14  | <14  | 1.40E+02                  | <2.15     |         | >5.34              | 30 Seconds   | <b>Pass</b> |