



Akrediteeritud L236

EVS-EN 14561:2006  
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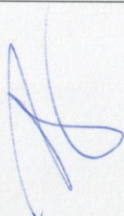
**Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (phase 2, step 2)**

## TEST REPORT no 310

**1. General information and material**

|                              |                                                              |
|------------------------------|--------------------------------------------------------------|
| 1.1 Client:                  | Medi-Sept Sp. z.o.o., Konopnica 159 c, 21-030 Motycz, Poland |
| Date of order:               | 2016/11/24                                                   |
| 1.2 Identification of sample |                                                              |
| Name of the product:         | VIRUTON PULVER                                               |
| Batch number:                | LOT: 160819_55                                               |
| Manufacturer:                | Medi-Sept Sp. z.o.o.                                         |
| Date of delivery:            | 2016/12/01                                                   |
| Storage conditions:          | room temperature and darkness                                |
| Apperance of the product:    | powder                                                       |
| Active substance:            | 44 % Sodium percarbonate, 26 % TAED (PAA)                    |

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**1.3 Test conditions**

|                              |                                                                                                                                    |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Test period:                 | 2016/12/07 – 2016/12/09                                                                                                            |
| Date of test:                | 2016/12/07                                                                                                                         |
| Product test concentrations: | 1,0 %; 2,0 %                                                                                                                       |
| Exposure time:               | 10 min; 30 min                                                                                                                     |
| Test temperature:            | 19,5 ± 0,5°C                                                                                                                       |
| Organic load:                | for clean conditions is bovine albumine 0,3 g/l;<br>for dirty conditions are bovine albumine 3,0 g/l and sheep erythrocytes 3 ml/l |
| Neutralizer:                 | Polysorbate 80, 30 g/l; Lecithin, 3 g/l; Sodium thiosulphate, 5 g/l                                                                |
| Temperature of incubation    | 36,5°C ± 0,5°C                                                                                                                     |
| Test organisms:              | Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442,<br>Enterococcus hirae ATCC 10541                               |

**2. Methods**

|                                      |                         |
|--------------------------------------|-------------------------|
| 2.1. Test method and its validation: | dilution neutralisation |
|--------------------------------------|-------------------------|

**3. Results**

see annex

**4. Conclusion**

In accordance with EN 14561:2006, product VIRUTON PULVER (LOT: 160819\_55) for instrument disinfection with concentration 1,0 % in 10 min and 30 min and 2,0 % in 10 min possesses bactericidal activity in carrier test at 20 °C under clean and dirty conditions for referenced strains Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541. The product VIRUTON PULVER demonstrates at least a 5 lg reduction.

Total 9 pages  
Annex on 7 pages

Maardu, 2016/12/09

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## Annex 1

**VALIDATION AND CONTROLS**

| Test organisms                          | Validation suspension<br>Nv |     |           | Experimental conditions control<br>A |     |           | Neutralizer control<br>B |     |           | Method validation<br>C<br>Concentr. 2,0 % |     |           |
|-----------------------------------------|-----------------------------|-----|-----------|--------------------------------------|-----|-----------|--------------------------|-----|-----------|-------------------------------------------|-----|-----------|
|                                         | Vc1                         | Vc2 | $\bar{X}$ | Vc1                                  | Vc2 | $\bar{X}$ | Vc1                      | Vc2 | $\bar{X}$ | Vc1                                       | Vc2 | $\bar{X}$ |
| Staphylococcus aureus<br>ATCC 6538      | 45                          | 41  | 43        | 50                                   | 43  | 47        | 38                       | 46  | 42        | 35                                        | 40  | 38        |
| Pseudomonas<br>aeruginosa ATCC<br>15442 | 79                          | 64  | 72        | 67                                   | 59  | 63        | 50                       | 53  | 52        | 61                                        | 65  | 63        |
| Enterococcus hirae<br>ATCC 10541        | 80                          | 69  | 75        | 77                                   | 70  | 74        | 75                       | 67  | 71        | 64                                        | 60  | 62        |

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## Annex 2

## TEST SUSPENSION

| Test organisms                    | Dilution step | Vc1  | Vc2  | N                                |
|-----------------------------------|---------------|------|------|----------------------------------|
| Staphylococcus aureus ATCC 6538   | -6            | 195  | 223  | $N = 2,1 \times 10^9 = \lg 9,32$ |
|                                   | -7            | 22   | 17   | $9,17 \leq \lg N \leq 9,77$      |
| Pseudomonas aeruginosa ATCC 15442 | -6            | >300 | >300 | $N = 4,85 \times 10^9 = \lg 9,7$ |
|                                   | -7            | 42   | 55   | $9,17 \leq \lg N \leq 9,77$      |
| Enterococcus hirae ATCC 10541     | -6            | >300 | >300 | $N = 4,0 \times 10^9 = \lg 9,6$  |
|                                   | -7            | 36   | 44   | $9,17 \leq \lg N \leq 9,77$      |

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## Annex 3

## WATER CONTROL

| Test organisms                    | Dilution step | Vc1  | Vc2  | Nw                                  |
|-----------------------------------|---------------|------|------|-------------------------------------|
| Staphylococcus aureus ATCC 6538   | -4            | >300 | >300 | $N = 3,8 \times 10^7 = \lg 7,58$    |
|                                   | -5            | 36   | 39   | $7,15 \leq \lg Nw \leq \lg N - 1,3$ |
| Pseudomonas aeruginosa ATCC 15442 | -4            | 135  | 150  | $N = 1,6 \times 10^7 = \lg 7,2$     |
|                                   | -5            | 14   | 18   | $7,15 \leq \lg Nw \leq \lg N - 1,3$ |
| Enterococcus hirae ATCC 10541     | -4            | >300 | >300 | $N = 4,8 \times 10^7 = \lg 7,7$     |
|                                   | -5            | 42   | 54   | $7,15 \leq \lg Nw \leq \lg N - 1,3$ |

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## Annex 4

## TEST 1 Staphylococcus aureus

| Test organism                   | Conditions | Concentration | Dilution | Vc1 | Vc2 | Na x 10 | Ig Na  | Ig R  | Cont. time |
|---------------------------------|------------|---------------|----------|-----|-----|---------|--------|-------|------------|
| Staphylococcus aureus ATCC 6538 | Clean      | 1,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,43 | 10 min     |
|                                 |            |               | -1       | 0   | 0   |         |        |       |            |
|                                 |            |               | -2       | 0   | 0   |         |        |       |            |
|                                 |            |               | -3       | 0   | 0   |         |        |       |            |
|                                 |            |               | 1        | 0   | 0   |         |        |       |            |
|                                 |            | 2,0 %         | -1       | 0   | 0   | < 140   | < 2.15 | >5,43 | 30 min     |
|                                 |            |               | -2       | 0   | 0   |         |        |       |            |
|                                 |            |               | -3       | 0   | 0   |         |        |       |            |
|                                 |            |               | 1        | 0   | 0   |         |        |       |            |
|                                 |            |               | -1       | 0   | 0   |         |        |       |            |
|                                 | Dirty      | 1,0 %         | -2       | 0   | 0   | < 140   | < 2.15 | >5,43 | 10 min     |
|                                 |            |               | -3       | 0   | 0   |         |        |       |            |
|                                 |            |               | 1        | 0   | 0   |         |        |       |            |
|                                 |            |               | -1       | 0   | 0   |         |        |       |            |
|                                 |            |               | -2       | 0   | 0   |         |        |       |            |
|                                 |            | 2,0 %         | -3       | 0   | 0   | < 140   | < 2.15 | >5,43 | 30 min     |
|                                 |            |               | 1        | 0   | 0   |         |        |       |            |
|                                 |            |               | -1       | 0   | 0   |         |        |       |            |
|                                 |            |               | -2       | 0   | 0   |         |        |       |            |
|                                 |            |               | -3       | 0   | 0   |         |        |       |            |

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## Annex 5

TEST 2 *Pseudomonas aeruginosa*

| Test organism                               | Conditions | Concentration | Dilution | Vc1 | Vc2 | Na x 10 | Ig Na  | Ig R  | Cont. time |
|---------------------------------------------|------------|---------------|----------|-----|-----|---------|--------|-------|------------|
| <i>Pseudomonas aeruginosa</i><br>ATCC 15442 | Clean      | 1,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 10 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |
|                                             |            |               | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 30 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |
|                                             |            | 2,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 10 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |
|                                             | Dirty      | 1,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 10 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |
|                                             |            |               | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 30 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |
|                                             |            | 2,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,05 | 10 min     |
|                                             |            |               | -1       | 0   | 0   |         |        |       |            |
|                                             |            |               | -2       | 0   | 0   |         |        |       |            |
|                                             |            |               | -3       | 0   | 0   |         |        |       |            |

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Annex 6  
 TEST 3 *Enterococcus hirae*

| Test organism                        | Conditions | Concentration | Dilution | Vc1 | Vc2 | Na x 10 | Ig Na  | Ig R  | Cont. time |
|--------------------------------------|------------|---------------|----------|-----|-----|---------|--------|-------|------------|
| <i>Enterococcus hirae</i> ATCC 10541 | Clean      | 1,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 10 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |
|                                      |            |               | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 30 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |
|                                      |            | 2,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 10 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |
|                                      | Dirty      | 1,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 10 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |
|                                      |            |               | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 30 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |
|                                      |            | 2,0 %         | 1        | 0   | 0   | < 140   | < 2.15 | >5,55 | 10 min     |
|                                      |            |               | -1       | 0   | 0   |         |        |       |            |
|                                      |            |               | -2       | 0   | 0   |         |        |       |            |
|                                      |            |               | -3       | 0   | 0   |         |        |       |            |

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## Annex 7

$$N = \frac{C}{(n1 + 0.1 n2) \times 10^{-7}}$$

$$Na = c \times 10^{-n}$$

$$Nw = c \times 10^{-n-5}$$

$$R = \lg Nw - \lg Na$$

N – is the number of cfu (colony forming unit) for 1 ml test suspension

Vc1, Vc2 - is the is number of cfu for 1 ml sample

n – is the number of Vc-values taken into account

Nw – water control

R – reduction

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