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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025.

Copy No.: 1
Issue No.: 1

Test report No. D6-2/2017

**SURGICAL HAND DISINFECTION (EN 12791) OF THE PRODUCT
VELODES SILK**

Sample ID: D6/2017
Sample name: **Velodes Silk**
Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Producer: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

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From pages: 6

Incoming date:
3.1.2017

Delivery date:
28.8.2017

Hodonín, 28.8.2017

Ing. Jana Šlitrová, Head of Laboratory



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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D6/2017
Rep No: 44
Sample name: **Velodes Silk**
Sampled: by client
Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz
Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.12.2016
Sample delivered: 3.1.2017
Testing date: 3.8. – 16.8.2017
Delivered amount: 500 ml
Batch No: 20161109_102
Page: 2

Subject of testing:
Surgical hand disinfection.

Identification of the sample:

Name of the product:	Velodes Silk
Batch number:	20161109_102
Date of manufacture:	09.11.2016
Expiry date:	09.11.2018
Manufacturer:	Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Incoming date:	3.1.2017
Storage conditions:	at room temperature in dark
Active compounds and concentrations in 100 g:	
CAS 64-17-5 Ethanol	63.7 g
CAS 67-63-0 Propan-2-ol	6.3 g

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 12791)

Effect:	immediate effect
Period of analysis:	3.8. – 16.8.2017
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Appearance of the products:	colourless liquid
The test concentration:	100% (concentrated)
The volume of the product:	2 x 3 ml / person, the total application volume is 6 ml
The application time:	2 x 1.5 min, the total application time is 3 min
The soap:	soft soap from linseed oil
Reference item:	CAS 71-23-8 1-Propanol p.a., batch number: K47123697611, expiry date: 31/10/2020, 60% (V/V)
The volume of the reference propan-1-ol used per person:	2 x 3 ml, according to reference surgical hand disinfection procedure, the total application volume is 6 ml
The application time:	2 x 1.5 min, according to reference surgical hand disinfection procedure, the total application time is 3 min
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Surgical hand disinfection procedure with product:	surgical hand disinfection in accordance with the standard (rubbing hands)
Test procedure:	
1.	Determination of the presence of microorganisms in the product
2.	Determination of the prevalue – number of cfu sampled immediately before treatment from the hand
3.	Determination of the postvalue – number of cfu sampled after treatment from the hand
4.	Expression and interpretation of results - reduction factor – ratio of prevalue and postvalue, generally expressed by decimal logarithms

The standard:

EN 12791:2016 Chemical disinfectants and antiseptics – Surgical hand disinfection - Test method and requirements (phase 2/step 2) February 2016

The Number of CFU in the tested product: 0 CFU/ml

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1. Experimental results

Tab. No. 1.1 Surgical hand disinfection procedure, rubbing hands – experimental results for RP and PP – immediate effect

Propan-1-ol 60% (V/V) 2×3 ml/osoba (6 ml), 2×1.5 min (3 min) – RP								Velodes Silk, 2×3 ml/osoba (6 ml), 2×1.5 min (3 min) – PP							
Volunteer		Number of CFU/plate from dilution 10 ^x						Volunteer		Number of CFU/plate from dilution 10 ^x					
No.	Hand	Prevalues			Postvalues			No.	Hand	Prevalues			Postvalues		
		10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁰	10 ⁻¹	10 ⁻²			10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁰	10 ⁻¹	10 ⁻²
1	left	>330	>330	<u>35</u>	>330	>330	<u>34</u>	1	left	>330	>330	<u>38</u>	>330	>330	<u>56</u>
	right	>330	>330	<u>47</u>	>330	>330	<u>39</u>		right	>330	>330	<u>35</u>	>330	>330	<u>65</u>
2	left	>330	>330	<u>42</u>	>330	<u>173</u>	<u>19</u>	2	left	>330	<u>113</u>	<14	>330	<u>144</u>	<u>16</u>
	right	>330	>330	<u>59</u>	>330	<u>199</u>	<u>23</u>		right	>330	<u>139</u>	<14	>330	<u>170</u>	<u>21</u>
3	left	>330	<u>85</u>	<14	>330	<u>47</u>	<14	3	left	<u>193</u>	<u>18</u>	<14	>330	<u>51</u>	<14
	right	>330	<u>73</u>	<14	>330	<u>41</u>	<14		right	<u>164</u>	<u>23</u>	<14	>330	<u>35</u>	<14
4	left	>330	<u>63</u>	<14	<u>188</u>	<u>20</u>	<14	4	left	<u>198</u>	<u>21</u>	<14	>330	<u>61</u>	<14
	right	>330	<u>92</u>	<14	<u>203</u>	<u>31</u>	<14		right	<u>213</u>	<u>31</u>	<14	>330	<u>74</u>	<14
5	left	>330	>330	<u>58</u>	>330	<u>194</u>	<u>20</u>	5	left	>330	>330	<u>78</u>	>330	>330	<u>65</u>
	right	>330	>330	<u>71</u>	>330	<u>211</u>	<u>16</u>		right	>330	>330	<u>102</u>	>330	>330	<u>80</u>
6	left	>330	>330	<u>58</u>	>330	<u>272</u>	<u>30</u>	6	left	>330	>330	<u>81</u>	>330	>330	<u>86</u>
	right	>330	>330	<u>63</u>	>330	<u>327</u>	<u>33</u>		right	>330	>330	<u>97</u>	>330	>330	<u>65</u>
7	left	>330	>330	<u>49</u>	<u>226</u>	<u>22</u>	<14	7	left	>330	>330	<u>42</u>	>330	<u>164</u>	<14
	right	>330	>330	<u>72</u>	<u>219</u>	<u>18</u>	<14		right	>330	>330	<u>47</u>	>330	<u>160</u>	<14
8	left	>330	>330	<u>50</u>	>330	<u>43</u>	<14	8	left	>330	>330	<u>72</u>	>330	<u>232</u>	<u>24</u>
	right	>330	>330	<u>61</u>	>330	<u>55</u>	<14		right	>330	>330	<u>43</u>	>330	<u>250</u>	<u>23</u>
9	left	>330	<u>71</u>	<14	<u>288</u>	<u>30</u>	<14	9	left	>330	>330	<u>70</u>	>330	>330	<u>70</u>
	right	>330	<u>85</u>	<14	<u>310</u>	<u>33</u>	<14		right	>330	>330	<u>96</u>	>330	>330	<u>62</u>
10	left	>330	>330	<u>34</u>	>330	>330	<u>59</u>	10	left	>330	>330	<u>77</u>	>330	>330	<u>52</u>
	right	>330	>330	<u>39</u>	>330	>330	<u>56</u>		right	>330	>330	<u>86</u>	>330	>330	<u>74</u>
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	right	>330	<u>241</u>	<u>24</u>	<u>249</u>	<u>26</u>	<14		right	>330	<u>58</u>	<14	<u>277</u>	<u>37</u>	<14
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	right	>330	>330	<u>48</u>	>330	<u>62</u>	<14		right	<u>217</u>	<u>24</u>	<14	<u>272</u>	<u>28</u>	<14
13	left	>330	<u>188</u>	<u>21</u>	<u>172</u>	<u>19</u>	<14	13	left	>330	>330	<u>55</u>	>330	>330	<u>47</u>
	right	>330	<u>232</u>	<u>22</u>	<u>199</u>	<u>27</u>	<14		right	>330	>330	<u>68</u>	>330	>330	<u>49</u>
14	left	>330	<u>81</u>	<14	<u>110</u>	<14	<14	14	left	>330	>330	<u>93</u>	>330	<u>262</u>	<u>27</u>
	right	>330	<u>65</u>	<14	<u>94</u>	<14	<14		right	>330	>330	<u>62</u>	>330	<u>256</u>	<u>26</u>
15	left	>330	<u>228</u>	<u>24</u>	<u>126</u>	<14	<14	15	left	>330	>330	<u>35</u>	>330	>330	<u>34</u>
	right	>330	<u>251</u>	<u>26</u>	<u>133</u>	<14	<14		right	>330	>330	<u>43</u>	>330	>330	<u>34</u>
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17	left	>330	>330	<u>63</u>	>330	>330	<u>33</u>	17	left	>330	>330	<u>71</u>	>330	>330	<u>37</u>
	right	>330	>330	<u>73</u>	>330	>330	<u>37</u>		right	>330	>330	<u>79</u>	>330	>330	<u>44</u>
18	left	>330	>330	<u>69</u>	>330	<u>132</u>	<u>18</u>	18	left	>330	>330	<u>82</u>	>330	>330	<u>62</u>
	right	>330	>330	<u>76</u>	>330	<u>162</u>	<u>20</u>		right	>330	>330	<u>78</u>	>330	>330	<u>67</u>
19	left	>330	>330	<u>34</u>	<u>284</u>	<u>30</u>	<14	19	left	>330	>330	<u>73</u>	>330	>330	<u>71</u>
	right	>330	>330	<u>36</u>	<u>317</u>	<u>31</u>	<14		right	>330	>330	<u>78</u>	>330	>330	<u>75</u>
20	left	>330	>330	<u>59</u>	>330	<u>63</u>	<14	20	left	>330	>330	<u>72</u>	>330	>330	<u>74</u>
	right	>330	>330	<u>77</u>	>330	<u>75</u>	<14		right	>330	>330	<u>84</u>	>330	>330	<u>70</u>
21	left	>330	>330	<u>61</u>	>330	>330	<u>53</u>	21	left	>330	>330	<u>70</u>	>330	>330	<u>71</u>
	right	>330	>330	<u>57</u>	>330	>330	<u>39</u>		right	>330	>330	<u>65</u>	>330	>330	<u>81</u>
22	left	>330	<u>248</u>	<u>23</u>	>330	>330	<u>35</u>	22	left	>330	>330	<u>56</u>	>330	>330	<u>71</u>
	right	>330	<u>273</u>	<u>27</u>	>330	>330	<u>39</u>		right	>330	>330	<u>50</u>	>330	>330	<u>75</u>
23	left	<u>220</u>	<u>23</u>	<14	<u>223</u>	<u>20</u>	<14	23	left	>330	<u>190</u>	<u>18</u>	>330	<u>38</u>	<14
	right	<u>239</u>	<u>25</u>	<14	<u>181</u>	<u>16</u>	<14		right	>330	<u>172</u>	<u>19</u>	>330	<u>45</u>	<14
24	left	<u>146</u>	<u>14</u>	<14	<u>152</u>	<u>15</u>	<14	24	left	>330	<u>119</u>	<14	>330	<u>61</u>	<14
	right	<u>133</u>	<u>16</u>	<14	<u>147</u>	<u>17</u>	<14		right	>330	<u>104</u>	<14	>330	<u>50</u>	<14

underlined = count used for further computation, >330 = not countable

Prepared by: Mgr. Alena Rýdlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D6/2017

Rep No: 44

Sample name: **Velodes Silk**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

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Batch No: 20161109_102

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Tab. No. 1.2 List of computed lg values (means of left and right hands) and lg reductions

Volunteer	Chronological Sequence	Reference handrub (RP) (Propan-1-ol 60% V/V)			Handrub with tested product (PP) (Velodes Silk)		
		lg prevalues	lg postvalues	lg R	lg prevalues	lg postvalues	lg R
1	RP → PP	4.61	3.56	1.05	4.56	3.78	0.78
2	RP → PP	4.70	3.27	1.43	4.10	3.20	0.90
3	RP → PP	3.90	2.64	1.26	3.26	2.63	0.63
4	RP → PP	3.89	2.30	1.59	3.32	2.83	0.49
5	RP → PP	4.81	3.30	1.51	4.95	3.86	1.09
6	RP → PP	4.78	3.48	1.30	4.95	3.88	1.07
7	RP → PP	4.78	2.34	2.44	4.65	3.21	1.44
8	RP → PP	4.74	2.69	2.05	4.76	3.38	1.38
9	RP → PP	3.89	2.48	1.41	4.92	3.82	1.10
10	RP → PP	4.56	3.76	0.80	4.91	3.80	1.11
11	RP → PP	4.36	2.34	2.02	3.72	2.45	1.27
12	RP → PP	4.72	2.85	1.87	3.38	2.45	0.93
13	PP → RP	4.32	2.28	2.04	4.79	3.68	1.11
14	PP → RP	3.86	2.01	1.85	4.89	3.41	1.48
15	PP → RP	4.38	2.11	2.27	4.59	3.53	1.06
16	PP → RP	4.03	1.52	2.51	4.79	3.27	1.52
17	PP → RP	4.83	3.54	1.29	4.88	3.61	1.27
18	PP → RP	4.86	3.18	1.68	4.90	3.81	1.09
19	PP → RP	4.54	2.48	2.06	4.88	3.86	1.02
20	PP → RP	4.83	2.84	1.99	4.89	3.86	1.03
21	PP → RP	4.77	3.66	1.11	4.83	3.88	0.95
22	PP → RP	4.41	3.57	0.84	4.72	3.86	0.86
23	PP → RP	3.36	2.30	1.06	4.26	2.62	1.64
24	PP → RP	3.15	2.18	0.97	4.05	2.74	1.31
Ø	Overall	4.38	2.78	1.60	4.50	3.39	1.10
s		0.49	0.63	0.51	0.56	0.51	0.28
n		24	24	24	24	24	24
Ø	RP → PP	4.48	2.92	1.56	4.29	3.28	1.01
s		0.37	0.53	0.46	0.69	0.57	0.29
n		12	12	12	12	12	12
Ø	PP → RP	4.28	2.64	1.64	4.70	3.51	1.19
s		0.58	0.71	0.56	0.28	0.44	0.25
n		12	12	12	12	12	12

lg R = decimal log reduction; RP → PP sequence: first RP, second PP; PP → RP sequence: first PP, second RP;

Ø = mean; s = standard deviation; n = number of values (= volunteers)

Difference of mean Rs (RP → PP): $1.56 - 1.01 = 0.55$; Difference of mean Rs (PP → RP): $1.64 - 1.19 = 0.45$;

Absolute difference of differences: $|0.55 - 0.45| = 0.10$

Acceptance criteria for test results:

Only if the results of the test procedure fulfil the following requirements, they shall be accepted for further evaluation, otherwise the test shall be repeated:

- A complete set of results from at least 23 volunteers shall be available. All complete set of results shall be used for further evaluation.
- The overall means of the lg prevalues for RP and PP shall be both at least 3.50.
- The absolute difference of mean differences between lg reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2.00.
- All quotients of weighted mean counts between 5 and 15.

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Tab. No. 1.3.1 Computation of individual differences of lg Rs of RP – PP

Volunteer	lg reduction (R)		Difference RP – PP
	Reference procedure (RP)	Product procedure (PP)	
1	1.05	0.78	0.27
2	1.43	0.90	0.53
3	1.26	0.63	0.63
4	1.59	0.49	1.10
5	1.51	1.09	0.42
6	1.30	1.07	0.23
7	2.44	1.44	1.00
8	2.05	1.38	0.67
9	1.41	1.10	0.31
10	0.80	1.11	-0.31
11	2.02	1.27	0.75
12	1.87	0.93	0.94
13	2.04	1.11	0.93
14	1.85	1.48	0.37
15	2.27	1.06	1.21
16	2.51	1.52	0.99
17	1.29	1.27	0.02
18	1.68	1.09	0.59
19	2.06	1.02	1.04
20	1.99	1.03	0.96
21	1.11	0.95	0.16
22	0.84	0.86	-0.02
23	1.06	1.64	-0.58
24	0.97	1.31	-0.34

Tab. No. 1.3.2 Computation for Hodges-Lehmann 97.5% upper confidence limits

	Sorted differences	Mean pairwise differences (d _i +d _{ii})/2											
		1.21	1.10	1.04	1.00	0.99	0.96	0.94	0.93	0.75	0.67	0.63	0.59
1	1.21	1.21 ¹											
2	1.10	1.16 ²	1.10 ⁶										
3	1.04	1.13 ³	1.07 ¹⁰	1.04 ¹³									
4	1.00	1.11 ⁴	1.05 ¹¹	1.02 ¹⁷	1.00 ²⁰								
5	0.99	1.10 ⁵	1.05 ¹²	1.02 ¹⁸	1.00 ²¹	0.99 ²⁴							
6	0.96	1.09 ⁷	1.03 ¹⁴	1.00 ¹⁹	0.98 ²⁶	0.98 ²⁷	0.96 ³²						
7	0.94	1.08 ⁸	1.02 ¹⁵	0.99 ²²	0.97 ²⁸	0.97 ³⁰	0.95 ³³	0.94 ³⁶					
8	0.93	1.07 ⁹	1.02 ¹⁶	0.99 ²³	0.97 ²⁹	0.96 ³⁴	0.95 ³⁴	0.94 ³⁷	0.93 ³⁹				
9	0.75	0.98 ²⁵	0.93 ³⁸	0.90 ⁴²	0.88 ⁴⁴	0.87 ⁴⁷	0.86 ⁴⁹	0.85 ⁵¹	0.84 ⁵⁴	0.75 ⁷⁹			
10	0.67	0.94 ³⁵	0.89 ⁴³	0.86 ⁴⁸	0.84 ⁵³	0.83 ⁵⁵	0.82 ⁶⁰	0.81 ⁶²	0.80 ⁶⁵	0.71	0.67		
11	0.63	0.92 ⁴⁰	0.87 ⁴⁶	0.84 ⁵²	0.82 ⁵⁹	0.81 ⁶¹	0.80 ⁶⁴	0.79 ⁶⁹	0.78 ⁷¹	0.69	0.65	0.63	
12	0.59	0.90 ⁴¹	0.85 ⁵⁰	0.82 ⁵⁸	0.80 ⁶³	0.79 ⁶⁸	0.78 ⁷⁰	0.77 ⁷³	0.76 ⁷⁷	0.67	0.63	0.61	0.59
13	0.53	0.87 ⁴⁵	0.82 ⁵⁷	0.79 ⁶⁷	0.77 ⁷²	0.76 ⁷⁶	0.75 ⁷⁸	0.74 ⁸²	0.73	0.64	0.60	0.58	0.56
14	0.42	0.82 ⁵⁶	0.76 ⁷⁵	0.73	0.71	0.71	0.69	0.68	0.68	0.59	0.55	0.53	
15	0.37	0.79 ⁶⁶	0.74 ⁸¹	0.71	0.69	0.68	0.67	0.66	0.65	0.56	0.52		
16	0.31	0.76 ⁷⁴	0.71	0.68	0.66	0.65	0.64	0.63	0.62	0.53			
17	0.27	0.74 ⁸⁰	0.69	0.66	0.64	0.63	0.62	0.61	0.60				
18	0.23	0.72	0.67	0.64	0.62	0.61	0.60	0.59					
19	0.16	0.69	0.63	0.60	0.58	0.58	0.56						
20	0.02	0.62	0.56	0.53	0.51	0.51							
21	-0.02	0.60	0.54	0.51	0.49								
22	-0.31	0.45	0.40	0.37									
23	-0.34	0.44	0.38										
24	-0.58	0.32											

The median is between the 12th and 13th value: $[0.59 + 0.53]/2 = 0.56$

The mean pairwise differences that do not exceed the median (here: 0.56) are computed. From table in EN 12791 of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for n=24 and a one-sided 0.025 level of significance, the critical value of 81 is found. Hence $e=81+1=82$. The pairwise differences are sorted in descending order (small exponents). The 82nd value is 0.74. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg Rs between RP and PP is 0.74, which is less than the agreed inferiority margin of 0.75. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded the test preparation PP is non-inferior to RP.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D6/2017
Rep No: 44
Sample name: **Velodes Silk**
Sampled: by client
Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz
Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.12.2016
Sample delivered: 3.1.2017
Testing date: 3.8. – 16.8.2017
Delivered amount: 500 ml
Batch No: 20161109_102
Page: 6



Interpretation:

Results of tests are in Tabs.
Surgical hand disinfection

The acceptance criteria for the test results were met.

The product **Velodes Silk**, batch No. 20161109_102, was tested according to EN 12791:2016 for **immediate effect** under test conditions: application volume 2 x 3 ml/person and application time 2 x 1.5 min. The Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg Rs between RP and PP is smaller (**0.74**) than the agreed inferiority margin of 0.75. Therefore the hypothesis of inferiority of **Velodes Silk** can be rejected and it can be concluded that the test preparation **Velodes Silk** is non-inferior to **propan-1-ol 60%**.

Conclusion:

The product **Velodes Silk** is suitable to be used as surgical hand disinfection for **immediate effect** under test conditions: application volume 2 x 3 ml/person and application time 2 x 1.5 min.

28.8.2017, Hodonín

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Ing. Barbora Stoklasková, Leader of Study

