

## QUALITY SYSTEM

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# EC-CERTIFICATE

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## Directive 93/42/EEC

Manufacturer: Goodpoint Chemicals OÜ  
Urda tee 3  
Jälgimäe  
Saku vald  
76404 Harjumaa  
Estonia

Coverage of Certificate: Design, manufacture and final inspection

Product category: Cleaning and disinfecting agents  
Wound irrigation solutions

Valid until: 27 May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 25 May 2021

  
\_\_\_\_\_  
Aliisa Siljander






  
\_\_\_\_\_  
Olli Kakkonen

Certificate no.  
**C-01-1153-776-21**

Notified Body no. 0537:  
Eurofins Expert Services  
Kivimiehentie 4  
FI-02150 ESPOO, FINLAND

**Attachment 1 to the Certificate number: C-01-1153-776-21**

|  |   |              |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|--|---|--------------|--|-------------|-------------------|--------------|--|--------------|-----|-------------|-----|---|------------------|-----|-------------------|-----|--|----------------|-----|--------------------|---------------------|-----|---------------------|-----|---------------------------|------------------|-----|-----------------|-----|--|-------------|-----|
| <b>Manufacturer:</b>   | Goodpoint Chemicals OÜ<br>Urda tee 3, Jälgimäe, Saku vald, 76404 Harjumaa<br>Estonia  |              |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| <b>Activity and product category:</b>  | Design, manufacture and final inspection of cleaning and disinfecting agents.<br>GMDN-code(s): 47631, 58077   |              |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| <b>Products:</b>   | <p>The certificate covers the following products:</p> <table><tr><td><i>Name</i></td><td><i>Brand name</i></td><td><i>Class</i></td></tr><tr><td rowspan="2">Cleaning and disinfecting agents for instruments</td><td>Globacid® ID</td><td>IIb</td></tr><tr><td>Globaclean®</td><td>IIb</td></tr><tr><td rowspan="2">Cleaning and disinfecting agents for surfaces</td><td>Globacid® SF med</td><td>IIa</td></tr><tr><td>Globaquat RTU med</td><td>IIa</td></tr><tr><td>Agent for disinfecting dental impressions and dentures</td><td>Globadent® RTU</td><td>IIb</td></tr><tr><td rowspan="2">Disinfecting wipes</td><td>Vitasept® Wipes med</td><td>IIa</td></tr><tr><td>Globaquat Wipes med</td><td>IIa</td></tr><tr><td rowspan="2">Disinfectant for surfaces</td><td>Globacid® AF med</td><td>IIa</td></tr><tr><td>Cyclone RTU med</td><td>IIa</td></tr><tr><td>Disinfecting agents for washing and servicing dental equipment suction systems</td><td>Suction 12N</td><td>IIa</td></tr></table> |              |  | <i>Name</i> | <i>Brand name</i> | <i>Class</i> | Cleaning and disinfecting agents for instruments | Globacid® ID | IIb | Globaclean® | IIb | Cleaning and disinfecting agents for surfaces | Globacid® SF med | IIa | Globaquat RTU med | IIa | Agent for disinfecting dental impressions and dentures | Globadent® RTU | IIb | Disinfecting wipes | Vitasept® Wipes med | IIa | Globaquat Wipes med | IIa | Disinfectant for surfaces | Globacid® AF med | IIa | Cyclone RTU med | IIa | Disinfecting agents for washing and servicing dental equipment suction systems | Suction 12N | IIa |
| <i>Name</i>  | <i>Brand name</i>   | <i>Class</i> |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Cleaning and disinfecting agents for instruments                               | Globacid® ID  | IIb          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|  | Globaclean®   | IIb          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Cleaning and disinfecting agents for surfaces                                  | Globacid® SF med  | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|  | Globaquat RTU med   | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Agent for disinfecting dental impressions and dentures                         | Globadent® RTU  | IIb          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Disinfecting wipes   | Vitasept® Wipes med   | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|  | Globaquat Wipes med   | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Disinfectant for surfaces  | Globacid® AF med  | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|  | Cyclone RTU med   | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| Disinfecting agents for washing and servicing dental equipment suction systems | Suction 12N   | IIa          |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
| <b>Date:</b>   | Valid from: 25 May 2021   |              |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |
|  | <div></div> <div>Aliisa SilianderOlli Kakkonen</div>   |              |  |             |                   |              |  |              |     |             |     |   |                  |     |                   |     |  |                |     |                    |                     |     |                     |     |                           |                  |     |                 |     |  |             |     |

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

**EUROFINS EXPERT SERVICES**




Medical Devices  
Kivimiehentie 4  
FI-02150 ESPOO, FINLAND

Business ID FI22975132

v. 1.1 / 10.9.2018



### Attachment 2 to the Certificate number: C-01-1153-776-21

|                                       |  |              |  |             |                   |              |                           |                      |     |
|---------------------------------------|--|--------------|--|-------------|-------------------|--------------|---------------------------|----------------------|-----|
| <b>Manufacturer:</b>                  | Goodpoint Chemicals OÜ<br>Urda tee 3, Jälgimäe, Saku vald, 76404 Harjumaa<br>Estonia   |              |  |             |                   |              |                           |                      |     |
| <b>Activity and product category:</b> | Design, manufacture and final inspection of wound irrigation solutions.<br>GMDN-code(s): 58931   |              |  |             |                   |              |                           |                      |     |
| <b>Products:</b>                      | <p>The certificate covers the following products:</p> <table><tr><td><i>Name</i></td><td><i>Brand name</i></td><td><i>Class</i></td></tr><tr><td>Wound irrigation solution</td><td>Globasept Wound Sol.</td><td>Ila</td></tr></table>  |              |  | <i>Name</i> | <i>Brand name</i> | <i>Class</i> | Wound irrigation solution | Globasept Wound Sol. | Ila |
| <i>Name</i>                           | <i>Brand name</i>  | <i>Class</i> |  |             |                   |              |                           |                      |     |
| Wound irrigation solution             | Globasept Wound Sol.   | Ila          |  |             |                   |              |                           |                      |     |
| <b>Date:</b>                          | Valid from: 25 May 2021  |              |  |             |                   |              |                           |                      |     |
|                                       | <div><br/>Aliisa Siljander</div> <div><br/>Olli Kakkonen</div> |              |  |             |                   |              |                           |                      |     |

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