

Projectmemo

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| To | : Oldelft Customers | Date | : 20180927 |
| | | Annexes: | : N.A. |
| Cc | : Stefan Roggeveen Rob Smalenburg | | |
| From | : R. Bons | Tel. | : 948 |

Subject : Oldelft Cleaners and Disinfectants Support Policy

1. Introduction

As a supplier of reusable medical devices, Oldelft recognizes its responsibility to provide its customers with an effective reprocessing procedure. After every use of our TEE probes, the probe requires thorough cleaning and disinfection. In our manuals we provide clear instructions for cleaning and disinfection of our respective products. Furthermore, we recognize that a broad range of chemical products for cleaning and disinfection is used by our end users. At Oldelft, we aim to support our customers and end-users by verifying the compliance of our TEE probes with an extensive, diverse and globally available range of cleaning and disinfection chemicals. The list of supported chemicals is published on our website www.oldelft.nl.

The list published on our website shows the brand name, the manufacturer, the active ingredients and the compliant products in our portfolio. Every new product that is developed by Oldelft will be tested for compatibility against this list, as well as any material change that we are forced to implement on our existing products.

Although the list covers a broad and diverse range of chemicals, we often receive requests from our customers or end-users to test a non-listed cleaning or disinfection product. In this document it is explained how we handle these requests.

2. Chemical compliance requests

If the chemical you want to use on our products is not listed on our website, and thus not yet supported by Oldelft, you can reach out to your sales representative with a request to add the chemical to the supported list. We will review this request internally, and respond with our decision as soon as possible. When we decide that we want to support this chemical, we will start with compatibility testing. This means that we will check if our products can safely withstand being exposed to the chemical over the course of its expected service life. These tests can take up to several weeks, and upon completion we will inform you of the result. In case our products are compatible with the requested chemical, we can add the chemical to our list of supported cleaners and disinfectants.

In order to support every chemical on our list, we need to test any design change or newly developed product against the full extent of the list. Therefore we have a number of requirements for any chemical that we choose the support.

- The chemical must be suitable to be used on invasive medical devices
- The chemical must be widely available
- An MSDS of the chemical needs to be publicly available
 - Based on the MSDS, the chemical will be reviewed on toxicity, CMR and REACH compliance

When Oldelft decides to support a chemical, we will test our products and any future design changes for compatibility free of charge as a service to our customers.

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| Project name: | Memo-no.: | Approval: | Sheet: |
| Oldelft Cleaners and Disinfectants Support Policy | CT -2018-0286 | RB | 1 of 2 |

Projectmemo

If for any reason we decide do not support a chemical, we may offer a compatibility test on a selection of our products. However, any future design change will not be tested against such chemicals.

3. Test Procedure

Oldelft products have been designed for a service lifetime of 5 years. We test compliance with all supported chemicals by doing a simulated lifetime test. Afterwards the test samples will be checked for any physical changes like decolorization, cracks or swelling. Then the test samples will be subjected to a dielectric strength and leakage current test to make sure our products remain safe after a lifetime of exposure to the tested chemical compound.

Currently, we do not automatically test for efficacy on all supported chemicals. If you wish to know the efficacy of a specific cleaner or disinfectant on our product, please contact your sales representative.

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| <i>Project name:</i> Oldelft Cleaners and Disinfectants Support Policy | <i>Memo-no.:</i> CT -2018-0286 | <i>Approval:</i> RB | <i>Sheet:</i> 2 of 2 |
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