

## **REACH Statement**

Statement concerning the relationship of Nitritex products to REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Under the regulations Nitritex Ltd is an importer of Articles into the EU.

Nitritex Ltd supports the objectives of the REACH regulation to improve the protection of human health and the environment from the risks posed by chemicals.

Nitritex products comply to the requirements of Annex XVII (including relevant amendments) related to the "restriction on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles".

With respect to the Candidate list with "Substances of very high concern (SVHC) for Authorization", published by the European Chemicals Agency (ECHA) and last amended on June 25th, 2020; and as required by Article 33 of the REACH Regulation, we confirm that our articles supplied to the EU-EMEA markets currently do not contain SVHC substances in excess of 0.1 % weight by weight **with exception of the products listed in Appendix A**.

We undertake to notify our customers if we receive information from our suppliers indicating that SVHC are used in any other of our products; if the concentration of SVHC exceeds the regulatory thresholds; or if substances that are added to the SVHC list in the future are above the threshold.

Peter Clarke Regulatory Affairs

13<sup>th</sup> July 2020 Dated

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## Appendix A

| Product Name           | Product<br>Code | Substance Name                | CAS<br>Number | wt/%  |
|------------------------|-----------------|-------------------------------|---------------|-------|
| BioClean Permaflow     | S-BPBP-1        | Lead                          | 7439-92-1     | >0.1% |
| Irradiated Cleanroom   |                 |                               |               |       |
| Ballpoint Pen          |                 |                               |               |       |
| BioClean Clearview     | BCAG            | Octamethylcyclotetrasiloxane, | 556-67-2,     | >0.1% |
| Autoclavable Goggles   |                 | Decamethylcyclotetrasiloxane, | 541-02-6,     |       |
| (Strap only)           |                 | Dodecamethylcyclohexasiloxane | 540-97-6      |       |
| BioClean Clearview     | BCGS1           | Octamethylcyclotetrasiloxane, | 556-67-2,     | >0.1% |
| Sterile Single Use     |                 | Decamethylcyclotetrasiloxane, | 541-02-6,     |       |
| Goggles (Strap only)   |                 | Dodecamethylcyclohexasiloxane | 540-97-6      |       |
| BioClean Vijon Sterile | BVGS            | Octamethylcyclotetrasiloxane, | 556-67-2,     | >0.1% |
| Single Use Goggles     |                 | Decamethylcyclotetrasiloxane, | 541-02-6,     |       |
| (Strap only)           |                 | Dodecamethylcyclohexasiloxane | 540-97-6      |       |

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