Declaration of Compliance for Silicone Tubing

The silicone tubing products provided by Fedrotek are platinum catalyzed silicone products. The product meets the following requirements:

- Does not contain hazardous substances that meet the limits specified in Appendix II of the EU RoHS Directive (EU) 2015/863.

- Meets the limit requirements for substances of high concern (SVHC) in REACH regulation (EC) 1907/2006.

- Meets the requirements of the "GB15979-2002 Hygiene Standard for Secondary Use of Sanitary Products".

- Complies with the requirements of the GB4806.11-2016 National Food Safety Standard for Rubber Materials in Contact with Food.

- Compliant with FDA 21 CFR 177.2600 standards for reusable rubber articles.

- Meets the requirements of Class VI in USP 43<88>standard.

- Passed the experimental evaluation of hemolysis, cytotoxicity, and skin sensitization in ISO10993 Medical Device Biology.

- Passed the FDA Class I medical device certification

- Certified by NSF 51 for food contact materials in the United States.

- No latex, no polycyclic aromatic hydrocarbons/PAHs, no nonylphenol/NP, no plasticizers (phthalates/PAEs), no 2,4 dichlorobenzene peroxide.

All ingredients in the product are derived from chemical synthesis and do not contain ingredients from animal or plant sources. The equipment used to manufacture this product is also not used to manufacture any products containing ingredients from animal or plant sources. The product does not contain BSE/TSE ingredients, has no pesticide residues, and meets Halal requirements.

This is to clarify.

Fedro Tek Co., Ltd

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