



To: Compliance

Subject: REACH, RoHS, MDR Declaration Statement

October 27, 2022

Dear Valued Customer,

Pelham Plastics, Inc. manufactures products in our facility in Pelham, New Hampshire. Please note that Pelham Plastics does not test products for compliance analysis. The information provided is based upon information from raw material and component suppliers, product composition, and Pelham Plastics manufacturing process knowledge.

**REACH Declaration**

In accordance with Article 59 of the European Union Regulation 1907/2006 on Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), the European Chemicals Agency periodically publishes lists identifying Substances of Very High Concern, or SVHCs. The SVHC list was updated on June 10, 2022, increasing the number of substances. The products manufactured by Pelham Plastics do not have any of these SVHCs intentionally added and therefore we believe are not contained above 0.1% by weight.

**RoHS 2 Declaration**

RoHS is defined in Directive 2011/65/EU and sets restrictions on the use of certain hazardous substances in electrical and electronic equipment. RoHS specifically restricts the concentration of the following materials: lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), and other polybrominated compounds to a level equal to or less than 0.1% by weight. It further restricts the use of cadmium to equal to or less than 0.01% by weight. On January 17, 2022, the European Delegated Directive (EU) 2015/863 added *six new substances* to the EU RoHS Directive. The restrictions for these additional substances enter into force on *January 17, 2022*, for all electrical and electronic equipment (EEE) excepting Category 8 and Category 9 products. The products manufactured by Pelham Plastics do not contain any of the RoHS-listed chemicals and is compliant with both RoHS Directives.

**Medical Devices Regulation**

The EU Medical Devices Regulation, MDR 2017/745, sets high standards of quality and safety for medical devices in order to meet common safety concerns regarding such products. The regulation specifically restricts certain carcinogenic, mutagenic, and reproductive toxins (CMR) and endocrine disrupting chemicals (EDC). CMRs and EDCs must be limited to a concentration below 0.1% by weight unless justification for their use can be provided. The products manufactured by Pelham Plastics do not contain any of the restricted substances listed in the MDR regulation.

The above statements are based on information available at this point in time and are believed to be accurate. Please consider this information confidential and privileged. Pelham Plastics will keep track of any relevant changes regarding this compliance certificate and keep customers informed of any updated information. These statements do not bind Pelham Plastics to any legal obligations. Pelham Plastics is providing these statements in good faith, but no warranties are made, and no liability is accepted.

Sincerely,

Kristin Schuller  
Quality Assurance Manager