

To: Compliance

Subject: REACH, RoHS, MDR Declaration Statement

February 16, 2023

Dear Valued Customer,

Pelham Plastics, Inc. is a contract manufacturer in Pelham, New Hampshire. As a contract manufacturer, Pelham Plastics is obliged to use materials specified by the legal manufacturer of the device and the responsibility for material compliance lies with the legal manufacturer. Any materials used in the manufacturing process that are not customer-directed are the responsibility of Pelham Plastics to ensure compliance to REACH/RoHS and MDR. 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 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/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. The materials used in manufacturing at Pelham Plastics do not contain any of the RoHS-listed chemicals and are 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 materials used in manufacturing at Pelham Plastics do not contain any of the restricted substances listed in the MDR regulation.

The above statements are based on information available now and are believed to be accurate. As new substances are added and/or reclassified (e.g., (EU) 2015/863, ATP18), Pelham Plastics will assess manufacturing materials and processes against the latest mandates 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