



To: Compliance

Subject: REACH, RoHS, MDR Declaration Statement

September 10, 2024

Dear Valued Customer,

The products that Pelham Plastics Inc manufactures are done so 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 Inc. manufacturing process knowledge.

REACH Declaration

Under REACH (Registration, Evaluation, Authorization and Restriction of Chemicals, EC 1907/2006) the European Union's chemical regulation, Article 33 requires a supplier of manufactured and imported articles to communicate Substances of Very High Concern (SVHC) to the next level in the supply chain if they are present above a concentration limit of 0.1 % on an article level. SVHC will be defined through the list of candidate substances for authorization that is produced by the European Chemicals Agency. 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 Declaration

The EU RoHS Directive 2011/65/EU and EU 2015/863 restrict ten substances and substance groups above a specific threshold at the homogeneous material level. It also allows certain exemptions for the use of the restricted substances in particular components and/or specific product applications. These specific exemptions are documented under Annex III and Annex IV of the 2011/65/EU Directive. Suppliers cannot assume that the exemptions automatically apply to their components, parts, materials, or products and are encouraged to request approval for use of any required EU RoHS exemptions via their Supply Chain representative. Improperly applying an exemption could be termed as a non-compliance leading to enforcement action and/or your disqualification as a supplier. The products manufactured by Pelham Plastics do not contain any of the RoHS listed chemicals and is compliant with both of the 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). CMR's and EDC's 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 Inc. 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 Inc. to any legal obligations. Pelham Plastics Inc is providing these statements in good faith, but no warranties are made, and no liability is accepted.

Sincerely,
Scott Smith
Scott Smith
Sales & Marketing Account Manager