21 Amflex Drive
Cranston, RI. 02921

8/24/2023

RE: **Declaration Statement**

Compliance Declaration Certification for material supplied by Nelipak

As a customer-centric custom thermoformer, Nelipak Healthcare Packaging is aware of our obligations with regards to laws and regulations regarding California Prop 65 (Including the Aug 2023 update) and EU Directive 2002/95/EC and subsequent amendments of the European Parliament and of the Council of the use of certain hazardous substances in electrical and electronic equipment (EEE) and REACH (Registration, Authorization and Restriction of Chemicals, European Union Regulation (EC) 1907/2006). We are providing you the following information to assist you in meeting your environmental policies and procedures.

Nelipak Healthcare Packaging does not add or use chemicals or substances of concern in our processes. We have obtained, and can provide you with our supplier's declarations that they, as the raw materials manufacturers, have the documentation that shows they are in compliance.

Nelipak Healthcare Packaging is a privately held company and therefore is not subject to many of the reporting requirements for many EU directives. However, as a supplier to many publicly-traded companies, we are committed to ensuring that our customers are able to comply with their business trading reporting requirements.

RoHS: Based on information obtained from our component suppliers, this document certifies that ALL Nelipak Healthcare Packaging products are "RoHS 2015/863" compliant and do not exceed the designated levels of Cadmium, Lead, Hexavalent Chromium, Mercury, Polybrominated Biphenyls or Polybrominated Diphenyl Ethers legislated under the provisions of the European Parliament and Council Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (2011/65/EU) and regulations promulgated there under, collectively, the "RoHS Regulations."

REACH: Based on information from raw material suppliers and product composition, Nelipak Healthcare Packaging's products are not intentionally manufactured or formulated with compounds and substances above the 0.1% threshold by weight listed in the REACH document titled "Candidate List of Substances of Very High Concern for Authorization" dated January 2023

This includes nanomaterials which are treated as any other chemicals.

Nelipak Healthcare Packaging has no notification obligations under Article 33, concerning these SVHCs listed above, as none are present in Nelipak Healthcare Packaging products and/or packaging are present below the 0.1% wt. /wt. concentration limit. Nelipak Healthcare

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Packaging products and packaging contain none of the Banned Substances listed in EU REACH Annex XVII. In addition, Nelipak Healthcare Packaging requires that its parts and material Suppliers provide Full Material Disclosure on their Products as part of the ongoing Material Declaration efforts.

EU Packaging directive and CEN Standard EN 13427:2004

This packaging is claimed to comply with the requirements of Article 8 of the EU Packaging Directive and CEN Standard EN 13427:2004 and therefore, is claimed to comply with the EU Packaging Directive (European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste).

The provisions of this certificate supersede and replace the provisions of all other certificates previously delivered relating to compliance with the RoHS and REACH Regulations.

In addition, Nelipak Healthcare Packaging and our company policies are fully supportive of global industry efforts to ensure manufacturing processes and supply chains are transparent and in full accordance with local and international regulatory and humanitarian laws.

Furthermore, we will immediately inform you in correspondence to REACH – Article 33 if any substance of content (as from a content of >0.1%) in our goods will be classified alarming by the European Agency for Chemicals ECHA. Based on the current status, however, we do not expect such an incidence.

BSE / TSE Compliance Declaration

Please be advised that Substances of Animal Origin are not intentionally added and are not present in the raw materials used in Nelipak Healthcare packaging manufacturing process to produce the product. Our product is 100% animal origin free. Therefore, there is no concern with regard to the BSE/TSE issue (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy).

PFAS

Our Product does not contain any Perfluoroalkyl Substances known as (PFAS)

Since all our Products are Plastic Packaging IPC1752 class D does not apply

We thank you for your continued support.

Sincerely,

Al Monfils

Al Monfils
Quality Assurance Manager
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