Date: 05/08/2023

Subject: MaxBlend2 Declaration on the Safety of the Materials

Scope: The purpose of this document is to provide clarity on the safety of the materials chosen to be used in the manufacturing of the MaxBlend2.

Background: The components of the MaxBlend2 have undergone testing by Claigan Inc. and have been found to be compliant to RoHS Directive 2011/65/EU and its amendment directives, in particular, Commission Delegated Directive 2015/863 to restrict four phthalates; and REACH Regulation 1907/2006 and its amendment regulations. This testing is documented in *QD-1161: Report, EU MDR (CMR and endocrine-disrupting) Conformity, MaxBlend Family.*

DCD-0049: Hazard Analysis, MaxBlend Family states that the materials are commonly used together without issue in respiratory applications. This combination is currently in use for Maxtec products with no risks identified. The Hazard Analysis also includes a Biocompatibility table which outlines the materials used in each component of the device and its exposure to the patient. It provides evidence that the materials chosen pose no rational risk in light of **ISO 10993 -1:2018** ***Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process***, taking into consideration the indications for use and contact duration. Abundant historical evidence also exists regarding the common use of these materials in medical and consumer devices where body contact is expected.

Conclusion: Based on the compliance of the materials used in the manufacturing of the components for the MaxBlend2 to the RoHS Directive 2011/65/EU and its amendment directives, in particular, Commission Delegated Directive 2015/863 to restrict four phthalates; and REACH Regulation 1907/2006 and its amendment regulations; and the historical evidence regarding the common use of these materials in medical devices, it can be declared that the materials are safe to be used on the patient and do not pose any additional risk taking into consideration the indications for use and contact duration.

Issued by Signature: Anvitha AnandRao Digitally signed by Anvitha AnandRao Date: 2023.05.09 08:47:49 -04'00' **Date**: 05/09/2023.

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