Final Report

Protocol Title: **Single Lot Release Ethylene Oxide Sterilization Validation for Sisu Global Health Filter and Accessory Kit**

Protocol #: 18-L002 LexaMed, Ltd.

Originator: Marcus Keller Date: 4/25/2018

LexaMed Approvals

Study Director:	Marcus Keller (Printed Name)	(Signature)	Date:	4/25/18
Technical Review:	David Brodersen (Printed Name)	(Signature)	Date:	4/25/18
Quality Assurance:	James Kulla (Printed Name)	(Signature)	Date:	4/25/18

1. Executive Summary

1.1. The purpose of this study was to define the 100% Ethylene Oxide (EO) sterilization parameters for the single lot release validation of the Sisu Global Health Filter and Accessory Kit (P/N: SGH – 8100), and detail procedures for test sample preparation, Biological Indicator (BI) placement, load configuration, laboratory testing and physical and microbiological acceptance criteria. The protocol execution was initiated on February 2, 2018 and completed on April 16, 2018.

1.2. The sterilization validation used an Overkill Approach in accordance with the requirements of the current sterilization standard - ISO 11135:2014 *Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices."*

1.3. The results from this validation support the capability of the sterilization cycle to deliver a six (6) spore log reduction (SLR) during the half cycle exposure to the validation load, therefore a routine cycle 55 exposure will provide a twelve (12) SLR during a routine cycle, or a minimum Sterility Assurance Level (SAL) of 10^{-6} to the product.

1.4. Additionally, the products under scope of this study met the ISO 10993-7 EO Residual limits for limited exposure product categorization when processed in Cycle 55 and receiving a minimum of 72 hours of heated aeration.

2. Scope

2.1. This protocol applied to the Sisu Global Health Filter and Accessory Kit (P/N: SGH – 8100) manufactured and packaged by Harbor Designs and Manufacturing, 1100 Wicomico St, Baltimore, MD -21230.

2.2. This single lot release EO sterilization validation was limited to the Sisu Global Health Filter and Accessory Kit (P/N: SGH – 8100), using the Half Cycle Overkill approach utilizing programmed Cycle 55 parameters and Chamber 4 at Cosmed Group in Franklin, NJ.

3. Background

3.1. The Sisu Global Health Filter and Accessory Kit is manufactured and packaged for Sisu Global Health as part of the Sisu Global Health Hemafuse product by Harbor Design and Manufacturing