

Schlegel Electronic Materials
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EU MDR DECLARATION OF CONFORMITY

1. Manufacturer Identification

Company: Schlegel Electronic Materials, Inc.
Address: 1600 Lexington Ave Ste 236A, Rochester NY 14606

2. Authorized Representative Identification

Name: Sean Vilavong
Title: QA/ISO Manager
Email: sean.vilavong@schlegelemi.com

3. Declaration of Conformity

The present declaration is written accordance to the requirements of MDR (EU) 2017/745 Article 19 and Annex IV.

We declare under our sole responsibility that the products supplied listed in section 3.1 have been assessed according to the procedure described in section 3.2 and meet all the applicable provisions of the following regulation:

Council Regulation (EU) 2017/745 on Medical Devices

2.1 Product Identification

Part Number:	Description

2.2 Conformity Assessment Process

MDR 2017/745 Annex IX, Conformity Assessment based on Quality Management System and assessment of technical documentation

Date of Issue: 10/12/2021

Name:

Sean Vilavong

Title:

QA/ISO Manager

Signature: