

EC Declaration of Conformity
(Council Directive 93/42/EEC)
Class 1 Medical Device
(non-sterile condition, non-measuring function)

We, **Bay Materials, LLC at 48450 Lakeview Blvd, Fremont, CA 94538, USA**

declare under our sole responsibility, that our product/s:

name: Thermoformable Plastic Sheet

type or model: Zendura

to which this declaration relates is in conformity with the essential requirements, especially the provisions and requirements of **Annex VII (Section VII.5 not applicable)**, of Council Directive **93/42/EEC**, as amended by Directive **2007/47/EC**, pertaining to medical devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at 29 Harley Street, London W1G 9QR, UK to act as our European Authorised Representative as defined in the aforementioned Directive

Date of issue: 10 OCT 2017

Place of issue: Fremont, CA USA

Signature: _____



Typed Name: Ray Stewart

Position/Title: Managing Member