inovo

Declaration of Conformity

Manufacturer: **(Name & Address)**	Inovo Inc. 401 Leonard Blvd N. Lehigh Acres, FL 33971
Notified Body:	BSI Group the Netherlands B.V (Amsterdam) Say Building John M. Keynesplein 9 1066 EP Amsterdam
Authorized Representative:	MDSS GmbH Schiffgraben 41 30175 Hanover, Germany (+49)-511-6262-8630

Inovo Inc. hereby declares that the product(s) specified below have been designed, manufactured, inspected, labeled and distributed in accordance with the applicable provisions of the EC Directive 93/42/EEC, as stated in Annex II without Section 4.

Product Name:	Oxymizer – Pendant Oxygen Conserving Device
Model:	P-224
Classification:	Class IIa / Rule 2:
Classification Rationale:	All non-invasive devices intended for channeling gases into the body
Applicable Standards:	Please refer to the Summary Technical Document for the listing of all applicable standards

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific list for all products concerned and bearing the CE 2797 mark. This Declaration of Conformity is within conformance to the 2007/47/EEC amendment.

Approval:
Signature: Sandy F _____ **Issue Date:** Nov. 13, 2019

Sandy Figueroa
Regulatory Affairs Manager