



## Declaration of Conformity

**Manufacturer:  
(Name & Address)** Inovo Inc.  
401 Leonard Blvd N.  
Lehigh Acres, Florida 33971  
USA

**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

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:** \_\_\_\_\_  
**Patricia Beja / Sr. Manager, Regulatory Affairs**

**Issue Date:** 02/15/2021