

# Declaration of Conformity

**Manufacturer:** Applied Medical Resources Corp.  
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**Product Designation:** Insufflation Needles

**Product Classification:** Class IIa, Rule 6

We hereby declare that the above mentioned devices are in compliance with the legislation of the Poland transposing the European Medical Device Directive 93/42/EEC, as stated in Annex II and as amended by Directive 2007/47/EC.



This declaration is based on:

## CE Product Certification

**Certificate No.:** 384  
**Issued by:** Polish Centre for Testing and Certification  
469 Pulawska Street  
02-844 Warsaw  
Poland  
**Date:** April 12, 2019

## Certification of a Quality System

**Complies to:** EN ISO 13485:2016  
**Issued by:** Underwriters Laboratories Inc.  
333 Pflingsten Road  
Northbrook, IL 60062

## Signed for and on behalf of Applied Medical Resources Corp.

**Place:** Rancho Santa Margarita, CA 92688

**Date, Name, Function:** Refer to signature page

# Device Identification

## Insufflation Needles

<b>Model(s)</b>	<b>Description</b>
C2201	Disposable Insufflation Needle, 120mm
C2202	Disposable Insufflation Needle, 150mm