

# Declaration of Conformity

**Manufacturer:** Applied Medical Resources Corp.  
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**Product Designation:** Electrosurgical Instruments

**Product Classification:** Class IIb, Rule 9

We hereby declare that the above mentioned devices are in compliance with the legislation of Poland transposing the 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.:** 1434-MDD-383/2021  
**Issued by:** Polish Centre for Testing and Certification  
469 Pulawska Street  
02-844 Warsaw  
Poland  
**Date of issue:** May 21, 2021

## Certification of a Quality System

**Complies to:** EN ISO 13485:2016  
**Issued by:** Underwriters Laboratories Inc.  
333 Pfingsten 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

## Electrosurgical Instruments

Model(s)	Description
EB010	Voyant® 5mm Fusion Device
EB030	Voyant Fine Fusion Device
EB040	Voyant Open Fusion Device
EB011	Voyant 5mm Fusion Device
EB015	Voyant Maryland Fusion Device
EB016	Voyant Maryland Fusion Device
EB017	Voyant Maryland Fusion Device
EB210	Voyant 5mm Fusion Device
EB230	Voyant Fine Fusion Device
EB240	Voyant Open Fusion Device
EB211	Voyant 5mm Fusion Device
EB215	Voyant Maryland Fusion Device
EB216	Voyant Maryland Fusion Device
EB217	Voyant Maryland Fusion Device