

Declaration of Conformity

Manufacturer: Applied Medical Resources Corp.
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Product Designation: Electrosurgical Generator

Product Classification: Class IIb, Rule 9

We hereby declare that the above mentioned devices are in compliance with the legislation of 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.: 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 Generator

Model(s)	Description
EA010	Voyant® Electrosurgical Generator
EA020	Voyant Electrosurgical Generator