



# CERTIFICATE

**EC Certificate No. 1434-MDD-383/2021**

**Full Quality Assurance System**

**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**Applied Medical Resources Corporation**

**22872 Avenida Empresa**

**Rancho Santa Margarita, California 92688**

**UNITED STATES**

for the design, manufacture and final inspection of  
medical devices, class IIb

**Sterile and non-sterile surgical instruments and accessories,  
electrosurgical generators and sterile electrosurgical  
handpieces, ureteral stents for vascular access, urology and  
general surgery**

*The list of medical devices covered by this certificate is provided in the annex 1*

complies with requirements  
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.05.2021 to 26.05.2024

The date of issue of the Certificate: 21.05.2021

The date of the first issue of the Certificate: 12.04.2019



Issued under the Contract No. MD-47/2021  
Application No: 654/2020  
Certificate bears the qualified signature.  
Warsaw, 21/05/2021  
Module H2/3/4/5  
FBM-26-E\_9

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.21  
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## ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No. 1434-MDD-383/2021**

*List of medical devices covered by the certificate:*

Product Family	Product Sub-Group	Model/Type
Disposable Dissectors	Disposable Dissectors	CYxxx
Laparoscopic Instruments	Epix Electrosurgical Probes with Smoke Evacuation	CW00x
Laparoscopic Scissors System	Laparoscopic Scissors System	CBxxx
RF Generator and Hand Piece	Voyant Bipolar Instruments	EB01X
		EB03X
		EB04X
		EB21X
		EB230
		EB240
	Voyant Electrosurgical Generator	EA010
		EA020
Surgical Clip Applier System	Surgical Clip Applier System	CA500
Urology Ureteral Stents	Sihouette Ureteral Stent with Monofilament Tether	B38xx



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Application No: No: 654/2020  
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Warsaw, 21/05/2021

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
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