



CERTIFICATE

EC Certificate No. 1434-MDD-384/2021
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 IIa

**Sterile and non-sterile surgical instruments and accessories,
surgical access ports, catheters for vascular access, urology
and general surgery**

The list of medical devices covered by this certificate is provided in the annex 1, 2, 3, 4

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: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021
Module H2/3/4/5

Anna
Małgorzata
Wyroba
Vice-President
Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.21
09:42:04 +02'00'



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Alexis Contained Extraction System	Alexis Contained Extraction System	GTBXX
Applied Anoscope	Anoscope	CNA21
Dilation Catheter	Cholangiography Catheter	C10xx
		CHO-040-xF
GelPOINT Path	Transanal Access Platform	CNOxx
	Transanal Access Platform with Insufflation Stabilization Bag	CNBxx
GELPOINT V-Path	GELPOINT V-Path Transvaginal Access Platform	C2A11
		C2A15
		C2A12
Insufflation Needles	Insufflation Needles	C22xx
Laparoscopic Access Systems	Disposable Fixation Trocars	CFxxx
		Disposable Trocars
	C07xx	
	CTFxx	
	C0Rxx	
	COQxx	
	CTRxx	
	CTSxx	
	CTBxx	
	CTNxx	
	DuraGold Plastic Reusable Cannulas	
	Stainless Steel Reusable Cannulas and Obturators	C04xx
		COExx
		COFxx
Kii Dissecting Balloon	C0Hxx	



Issued under the Contract No. MD-47/2021
 Application No: 655/2020
 Certificate bears the qualified signature.
 Warsaw, 21/05/2021

Anna
 Małgorzata
 Wyroba
 Vice-President

Elektronicznie
 podpisany przez Anna
 Małgorzata Wyroba
 Data: 2021.05.21
 09:42:37 +02'00'



ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Laparoscopic Instruments	Laparoscopic Graspers	C41xx
		C42xx
Pneumostasis Ports	Trocar Seals	C0Lxx
		C0600
		420206-xx
		400161-xx
Pneumostasis Ports and Kits	Alexis Laparoscopic system	C87xx
	GelPort Hand Access Laparoscopic System and GelPoint Advanced Access Platform	C8XX2CE
		CNGL2
		CNGL3
Retractors	Wound Protector/Retractors	G63xx
		C83xx
		C84xx
		C85xx
		HRxxx
Suction Irrigators	Epix Probes	C72xx
	Epix Suction Irrigation Tubing Sets	C6xxx
Surgical Clamps and Inserts	Stealth Surgical Clamp Inserts	A0Axx
		A0Cxx
		A0Gxx
	Surgical Clamp Inserts	G-xx00
		G-xx05
		G-xx55
		A080x
		G-xx50



Issued under the Contract No. MD-47/2021
 Application No: 655/2020
 Certificate bears the qualified signature.
 Warsaw, 21/05/2021

Anna
 Małgorzata
 Wyroba

Elektronicznie
 podpisany przez Anna
 Małgorzata Wyroba
 Data: 2021.05.21
 09:43:16 +02'00'

Vice-President



ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Surgical Clamps and Inserts	Stealth Surgical Clamps	A32xx
	Surgical Clamps	A33xx
Surgical Clips	Custom Surgical Spring Clip	G-60xx
		G-12xx
		AVD-6025
	Stealth Surgical Spring Clip	A160x
		A165x
	Surgical Handless Clamps	G-11xx
		A2201
	Surgical Spring Clip	A161x
A1801		
Tissue Retrieval System	Tissue Retrieval System	CD00x
Urology Introducer Sheaths Access Sheaths	Forte AxP Access Sheath	B73xx
	Forte AxP Access Sheath Size 1	B72xx
	Forte AxP Access Sheath Size 2	B70xx
	Forte AxP Access Sheath Size 3	B71xx
Vascular Catheters	Biliary Catheter	A47xx
		CB05xxx8
		CB062313
	Irrigation Catheter	IRR-xxx-xxF
		IRR-xxx-xF
	Latis Graft Cleaning Catheter	A4Gxx
	Python Embolectomy Catheter	A4E0x
		CE0xx0DR
Regular Tip Embolectomy Catheter	A440x	



Issued under the Contract No. MD-47/2021
Application No: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.21
09:43:46 +02'00'



ANNEX 4 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Vascular Catheters	Regular Tip Embolectomy Catheter	CE0xx0
	Spring Tip Embolectomy Catheter	A4F0x
		CE0xx0ST
	Thrombectomy Catheter	A45xx
CT0xx0xx		

CE 1434

Issued under the Contract No. MD-47/2021
Application No: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.21
09:44:17 +02'00'