

Declaration of Conformity

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Product Designation: Laparoscopic Trocars
Disposable Trocars

Product Classification: Class IIa, Rule 7

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.: 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 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

Laparoscopic Trocars

Disposable Trocars

Model	Description
C0701	Shielded Obturator, 11 x 100mm
C0702	Shielded Obturator, 12 x 100mm
C0704	Conductive Stability Cone, 11mm
C0705	Conductive Stability Cone, 12mm
C0706	Non-Conductive Stability Cone, 11mm
C0707	Non-Conductive Stability Cone, 12mm

Kii® Access System

Model	Description
C0Q07	5x100mm Kii Sleeve, Smooth
C0Q10	5x100mm Kii Sleeve, Threaded
C0Q19	8x100mm Kii Access System with Optical Separator Obturator (Threaded or Z-Thread)
C0Q20	5x100mm Kii Balloon Blunt Tip System
C0Q45	5x55mm Kii Threaded, Non Shielded Bladed (Dual)
C0Q46	5x100mm Kii Non-Threaded, Non Shielded Bladed (Dual)
C0Q47	5x100mm Kii Threaded, Non Shielded Bladed (Dual)
C0Q48	5x55mm Kii Shielded Bladed, Non-Threaded Access System
C0Q49	5x100mm Kii Shielded Bladed, Non-Threaded Access System
C0Q51	5x55mm Kii Shielded Bladed, Threaded Access System
C0Q52	5x100mm Kii Shielded Bladed, Threaded Access System
C0Q56	5x150mm Kii Shielded Access System, Non-Threaded (Dual)
C0Q60	8x100mm Kii Non-Threaded Shielded Bladed Access System
C0Q61	8x100mm Kii Access System with Shielded Bladed Obturator (Threaded or Z-Thread)
C0Q87	5x55mm Kii Non-Threaded Separator System
C0Q88	5x100mm Kii Non-Threaded Separator System
C0Q89	5x150mm Kii Non-Threaded Separator System
C0Q91	5x100mm Kii Threaded Separator System
C0Q93	5x55mm Kii Non-Threaded Separator Dual Pack
C0Q94	5x100mm Kii Non-Threaded Separator Dual Pack
C0R24	11x100mm Kii Non-Threaded Optical Access System w/Handle
C0R25	11x100mm Kii Threaded Optical Access System w/Handle
C0R32	12x100mm Kii Non-Threaded Optical Access System w/Handle
C0R37	15x100mm Kii Access System with Optical Separator Obturator (Threaded or Z-Thread)
C0R38	15x150mm Kii Non-Threaded Optical Access System
C0R39	15x150mm Kii Access System with Optical Separator Obturator (Threaded or Z-Thread)

C0R47 12x100mm Kii Balloon Blunt Tip System
 C0R50 12X130mm Kii Balloon Blunt Tip System
 C0R62 11x100mm Kii Shielded System Non-Threaded
 C0R63 11x100mm Kii Shielded System Threaded
 C0R67 12x100mm Kii Shielded System Threaded
 C0R69 12x150mm Kii Threaded Shielded Bladed
 C0R80 11x60mm Kii Non-Threaded Optical Access System
 C0R81 11x60mm Kii Z-Thread Access Systems with Optical Separator Obturators
 C0R83 12x60mm Kii Z-Thread Access Systems with Optical Separator Obturators
 C0R85 12x100mm Kii Blunt Tip Access System
 C0R95 12x100mm Kii Blunt Tip Access System, small cone
 CTB01 5X150mm Kii Z-Thread Access Systems with Shielded Bladed Obturators
 CTB03 5X100mm Kii Z-Thread Access Systems with Shielded Bladed Obturators
 CTB05 5X55mm Kii Z-Thread Access Systems with Shielded Bladed Obturators
 CTB10 5X150mm Kii Z-Thread Dual Packs with Shielded Bladed Obturators
 CTB12 5X100mm Kii Z-Thread Dual Packs with Shielded Bladed Obturators
 CTB14 5X55mm Kii Z-Thread Dual Packs with Shielded Bladed Obturators
 CTB21 5x55mm Kii Low Profile Bladed Access System, Z-Thread
 CTB22 5x100mm Kii Low Profile Bladed Access System, Z-Thread
 CTB23 5x55mm Kii Low Profile Bladed Access System, Z-Thread Dual Pack
 CTB24 5x100mm Kii Low Profile Bladed Access System, Z-Thread Dual Pack
 CTB31 11X150mm Kii Z-Thread Access System with Shielded Bladed Obturator
 CTB33 11X100mm Kii Z-Thread Access System with Shielded Bladed Obturator
 CTB35 11x100mm Kii Z-Thread Shielded Bladed Dual Pack
 CTB37 5x100mm Kii Bladed Z-Thread Dual Packs
 CTB71 12X150mm Kii Z-Thread Access System with Shielded Bladed Obturator
 CTB73 12X100mm Kii Z-Thread Access System with Shielded Bladed Obturator
 CTB75 12x100mm Kii Z-Thread Shielded Bladed Dual Pack
 CTF35 11x100mm Kii Fios Z-Thread Dual Pack
 CTF75 12x100mm Kii Fios Z-Thread Dual Pack
 CTN03 5X100mm Kii Z-Thread Access Systems with Separator Obturators
 CTN12 5X100mm Kii Z-Thread Dual Packs with Optical Separator Obturators
 CTR01 5X150mm Kii Z-Thread Access Systems with Optical Separator Obturators
 CTR03 5X100mm Kii Z-Thread Access Systems with Optical Separator Obturators
 CTR05 5X55mm Kii Z-Thread Access Systems with Optical Separator Obturators
 CTR10 5X150mm Kii Z-Thread Dual Packs with Optical Separator Obturators
 CTR12 5X100mm Kii Z-Thread Dual Packs with Optical Separator Obturators
 CTR14 5X55mm Kii Z-Thread Dual Packs with Optical Separator Obturators
 CTR21 5x55mm Kii Low Profile Optical Access System, Z-Thread
 CTR22 5x100mm Kii Low Profile Optical Access System, Z-Thread
 CTR23 5x55mm Kii Low Profile Optical Access System, Z-Thread Dual Pack
 CTR24 5x100mm Kii Low Profile Optical Access System, Z-Thread Dual Pack
 CTR31 11X150mm Kii Z-Thread Access System with Optical Separator Obturator
 CTR32 11X150mm Kii Z-Thread Access System with Optical Separator Obturator,
 Handled
 CTR33 11X100mm Kii Z-Thread Access System with Optical Separator Obturator

CTR34 11X100mm Kii Z-Thread Access System with Optical Separator Obturator, Handled

CTR71 12X150mm Kii Z-Thread Access System with Optical Separator Obturator

CTR72 12X150mm Kii Z-Thread Access System with Optical Separator Obturator, Handled

CTR73 12X100mm Kii Z-Thread Access System with Optical Separator Obturator

CTR74 12X100mm Kii Z-Thread Access System with Optical Separator Obturator, Handled

CTS01 5X150mm Kii Access System, Z-Thread Sleeve

CTS02 5X100mm Kii Access System, Z-Thread Sleeve

CTS03 5X55mm Kii Access System, Z-Thread Sleeve

CTS11 11X150mm Kii Sleeve, Z-Thread

CTS12 11X100mm Kii Sleeve, Z-Thread

CTS21 12X150mm Kii Sleeve, Z-Thread

CTS22 12X100mm Kii Sleeve, Z-Thread

CTS28 5x55mm Kii Low Profile Sleeve, Z-Thread

CTS29 5x100mm Kii Low Profile Sleeve, Z-Thread

CTF01 5x150mm Kii Z-Thread Access Systems with Fios Obturators

CTF03 5x100mm Kii Z-Thread Access Systems with Fios Obturators

CTF04 5x100mm Kii Z-Thread Access Systems with Fios Obturators, Handled

CTF12 5x100mm Kii Z-Thread Dual Packs with Fios Obturators

CTF31 11x150mm Kii Z-Thread Access System with Fios Obturator

CTF33 11x100mm Kii Z-Thread Access System with Fios Obturator

CTF34 11x100mm Kii Z-Thread Access System with Fios Obturator, Handled

CTF71 12x150mm Kii Z-Thread Access System with Fios Obturator

CTF73 12x100mm Kii Z-Thread Access System with Fios Obturator

CTF74 12x100mm Kii Z-Thread Access System with Fios Obturator, Handled

CFB01 5x150mm Kii Shielded Bladed Advanced Fixation System

CFB03 5x100mm Kii Shielded Bladed Advanced Fixation System

CFB12 5x100mm Kii Advanced Fixation Shielded Bladed Dual Packs

CFB31 11x150mm Kii Shielded Bladed Advanced Fixation System

CFB33 11x100mm Kii Shielded Bladed Advanced Fixation System

CFB37 5x100mm Kii Bladed Advanced Fixation Dual Packs

CFB71 12x150mm Kii Shielded Bladed Advanced Fixation System

CFB73 12x100mm Kii Shielded Bladed Advanced Fixation System

CFF01 5x150mm Kii Fios First Entry Advanced Fixation System

CFF03 5x100mm Kii Fios First Entry Advanced Fixation System

CFF04 5x100mm Kii Fios First Entry Advanced Fixation Cannula with Fios Obturator, Handled

CFF05 5x75mm Kii Fios First Entry Advanced Fixation System

CFF10 5x150mm Kii Advanced Fixation Fios Dual Packs

CFF12 5x100mm Kii Advanced Fixation Fios Dual Packs

CFF14 5x75mm Kii Advanced Fixation Fios Dual Packs

CFF31 11x150mm Kii Fios First Entry Advanced Fixation System

CFF33 11x100mm Kii Fios First Entry Advanced Fixation System

CFF34 11x100mm Kii Fios First Entry Handled Advanced Fixation System

CFF71	12x150mm Kii Fios First Entry Advanced Fixation System
CFF73	12x100mm Kii Fios First Entry Advanced Fixation System
CFF74	12x100mm Kii Fios First Entry Handled Advanced Fixation System
CFF75	12x75mm Kii Fios First Entry Advanced Fixation System
CFR01	5x150mm Kii Optical Advanced Fixation System
CFR03	5x100mm Kii Optical Advanced Fixation System
CFR10	5x150mm Kii Advanced Fixation Optical Dual Packs
CFR12	5x100mm Kii Advanced Fixation Optical Dual Packs
CFR31	11x150mm Kii Optical Advanced Fixation System
CFR33	11x100mm Kii Optical Advanced Fixation System
CFR34	11x100mm Kii Optical Separator Obturator (Handled) with Advanced Fixation Sleeve
CFR39	15x150mm Kii Optical Advanced Fixation System
CFR71	12x150mm Kii Optical Advanced Fixation System
CFR73	12x100mm Kii Optical Advanced Fixation System
CFR74	12x100mm Kii Optical Separator Obturator (Handled) with Advanced Fixation Sleeve
CFS01	5x150mm Kii Sleeve, Advanced Fixation
CFS02	5x100mm Kii Sleeve, Advanced Fixation
CFS03	5x75mm Kii Sleeve, Advanced Fixation
CFS11	11x150mm Kii Sleeve, Advanced Fixation
CFS12	11x100mm Kii Sleeve, Advanced Fixation
CFS21	12x150mm Kii Sleeve, Advanced Fixation
CFS22	12x100mm Kii Sleeve, Advanced Fixation

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RELEASED

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