



Product Families - Approved for CE Marking

Uterine Manipulation Devices

Product Family Name	Applicable P/N's to be CE Marked
The RUMI System®	UMH600, UMH650, UMW676, UMB678, UMG670, UML516, UMO672 & UMY514
KOH Colpotomizer™ Sys. (Colpo-Pneumo Occluder™ & KOH Cup™) [RUMI Sys.® Accessories]	KCS-SET, KCS-30, KCS-35, KCS-40, KCP-SET, KCP-30-2, KCP-30-6, KCP-35-2, KCP-35-6, KCP-40-2, KCP-40-6, KCS-KIT, KCP-KIT, CPO-6, & KCT. <u>Accessories for RUMI II Handle:</u> KC-RUMI-25, KC-RUMI-30, KC-RUMI-35, KC-RUMI-40, KCS-RUMI-25, KCS-RUMI-30, KCS-RUMI-35. KCS-RUMI-40
Kronner Manipujector®	6003
(UPS) - Uterine Positioning System	371560-01, UMST-C, 371552-03, 371553-01, 400245-01
RUMI Arch	UMH750
RUMI Arch	UMH750
Sacrocolpopexy/Sacrocolpexy Tips	SACRO-1, SACRO-1S, SACRO-1C
Arch Koh-Efficient	KCS-ARCH-30, KCS-ARCH-35, KCS-ARCH-40
KC-SIZER	KC-SIZER

Laparoscopic Port-Site Closure

Product Family Name	Applicable P/N's to be CE Marked
Carter-Thomason's Suture Kit Device (Disposable Laparoscopy Devices)	C-T Closure Kit: CTI-1015N C-T Closure: CTI-512N C-T Closure XL: CTXL Pilot Guides: PG-5/10 15mm Pilot Guide: PG-15S

Self-Retaining Retractors

Product Family Name	Applicable P/N's to be CE Marked
Lone Star Medical Products, Inc. Devices	<u>Elastic Stay Hooks, Sterile, Single Use [3xxx Series] & [3xxxG Series]:</u> 3329-XG, 3330-XG, 3331-XG, 3332-XG, 3333-XG, 3334-XG, 3335-XG, <u>Retractors, Sterile, Single Use [33xxG Series]:</u> 3715 & 3301G, 3302G, 3304G, 3307G, 3308G, 3309G, 3310G. <u>AL [11xx Series] & SS [22xx Series] Retractors, Non-Sterile, Reusable :</u> 1104, 1107, 1110, 2200, 2201. <u>Dilamezinsert, Sterile, Single Use:</u> DMI-12G

C-Section Retractors and Wound Protection

Product Family Name	Applicable P/N's to be CE Marked
Mobius Retractor	900-500, -508, -515, -517, -520

Secondary Trocars

Product Family Name	Applicable P/N's to be CE Marked
Trocar Cannula	900-800, -801, -802, -803, -820, -821, -822, -823, -840, -841, -842, -844,- 845, -846, -847, -850, -851,

Laparoscopic Smoke Evacuation

Product Family Name	Applicable P/N's to be CE Marked
SeeClear Laparoscopic Smoke Evacuation Systems	SC062500, SC082500

Fetal and Vascular Dopplers and Probes

Product Family Name	Applicable P/N's to be CE Marked
Tria® w / Fetal & Vascular Ultrasound Diagnostic Dopplers (Medasonics)	T334, T334-D, T345, T345-D, T336, T336-D

LEEP Instruments

Product Family Name	Applicable P/N's to be CE Marked
Prima Series® LEEP Specula	PSV-1L & PSV-2L

LEEP System and Accessories

Product Family Name	Applicable P/N's to be CE Marked
LEEP Electrodes	R2510, R2020, R2015, R2010, R2008, R1515, R1507, R1505, R1010, R1007, S1010, S1007, S1004, V1004, N1200, N0550, N2512, N2555, B0512, B0555, B0312. END
LEEP 1000 Generator	L1000A,
FCBE (Fischer Cone Biopsy Excisor)	900-150, -151, -152, -154, -155, -156, -157, -158.

Stainless Steel Instruments

Product Family Name	Applicable P/N's to be CE Marked
Stainless Instruments from GmbH w/Mfgr's CE Mark	64-XXX, 66-XXX, F-XXX, Series [w/exception of 64-376 which is NOT Stainless Steel.]

Endometrial Samplers

Product Family Name	Applicable P/N's to be CE Marked
Endometrial Suction Curette: Milex's Pipet Curet [Annex V]	MX140, MX145, MX150
Pipelle	8200
Milex EXPLORA I & II	MX120, MX124, MX130

Cervical and Endocervical Samplers

Product Family Name	Applicable P/N's to be CE Marked
Cytology Sampling Devices Medscand's [Annex V] NON-STERILE	Medscand Sample Collection Kit: 02500* Cytobrush Plus®: C0004, C0005, C0021 Cytobrush Plus® GT: C0104, C0105, C0121 Cytobrush Plus® GT, Scored: C0305 Pap-Perfect® Spatula: 11080
Cytology Sampling Devices Medscand's [Annex V] STERILE	Cytobrush Plus®: C0012 Sterile. Cytobrush Plus® GT: C0112 Sterile. Uterobrush®: E0001 Sterile

H/S Catheters

Product Family Name	Applicable P/N's to be CE Marked
Ackrad™ Product Line Extension	H/S Catheter, H/S Elliptosphere™, Tampa Catheter, & H/S Catheter w/Integrated Stylet: 61-5005, 61-5007, 61-4005, 61-4005S, 61-2005, 61-0020, 61-3005, 61-3007, 19610, 19611.

Pessaries

Product Family Name	Applicable P/N's to be CE Marked
Milex Vaginal Pessaries [Annex V]	MXFIT, MXPEC, MXKPEC, MXPECH, MXKPECH, MXPECT, MXKPECT, MXPINF, MXKPINF [plus sizes]
Milex Vaginal Pessaries [Annex II]	MXPDO, MXKPDO, MXPGS, MXKPGS, MXPGSK, MXKPGSK, MXPGRS, MXKPGRS, MXPGE, MXKPGE, MXPGSS, MXKPGSS, MXPEH, MXKPEH, MXPHSK, MXKPHSK, MXPEHK, MXKPEHK, MXPHS, MXKPHS, MXPCOND, MXKPCOND, MXPCONDS, MXKPCONDS, MXPCON, MXKPCON, MXPREG, MXKPREG, MXPER, MXKPER, MXPRS, MXKPRS, MXPRSK, MXKPRSK, MXPERK, MXKPERK, MXPRI, MXKPRI, MXPSH, MXKPSH, MXPES, MXKPES. + P/N's moved from #18 to here: MXPGFs, MXPGSSFS, MXPRGEFS, MXPRGSSFS, MXPRSFS.
Pessary Fitting Kits	MXFIT, MXFIT-CA, MXFIT0012 thru MXFIT0025, MXFIT0801 thru MXFIT0812 & MXFIT0072

Diaphragms

Product Family Name	Applicable P/N's to be CE Marked
Milex Contraceptive Diaphragm FITTING SETS [Annex V]	MXWSFS, MXWFFS
Milex Vaginal Diaphragms [Annex II]	MXWS, MXWF

Cryosurgical Systems

Product Family Name	Applicable P/N's to be CE Marked
LM-900 Cryosurgical System and Probes	50501, 50502, 50003, 50007, 50008, 50009, 50011, 50012, 50101 thru 50115
CE 2000 Ophthalmic Cryosurgery System	<p>SYSTEM: CE-2000</p> <p><u>PROBES:</u></p> <p>Cataract: 126, 127, 128, 147.</p> <p>Pediatric Retinal: 120, 121, 122, 123, 148, 149.</p> <p>Retinal & Accessories: 124, 125, 139, 143, 144, 708-4, 708-5.</p> <p>Super Cool: 142, 161, 162, 163, 164, 165, 166, 167.</p> <p>Trichiasis: 171, 172, 173.</p> <p>Vitreous Intraocular: 134.</p>

Urodynamics

Product Family Name	Applicable P/N's to be CE Marked
Lumax TS Pro Fiberoptic Cystometry System and Sterile Fiberoptic Catheters [Annex V]	<p>TSBAS [Basic, includes monitor, transducers, catheters, accessories, & user manual].</p> <p>TSADV [is the Basic System plus Lumax TS Pro Software, Laptop, & USB Cable].</p> <p>TSAUP [upgrades the TSBAS to the TSADV & includes Lumax TS Pro Software, Laptop, & USB Cable].</p> <p>Catheters, Bladder, w/Infusion Lumen: 10307-010, 10307-005.</p> <p>Catheters, Abdominal: 10307-009.</p> <p>Custom Tubing Sets: 20108-000.</p> <p>S-Series Transmission Cable: 10310-000.</p> <p>Lumax TS Pro Monitor: 53305.</p> <p>Uroflow Transducer: 53309.</p> <p>Volume Infused Transducer: 53310.</p> <p>Remote Footswitch Marker: 53326.</p> <p>Remote Hand-Held Marker: 53298.</p>

Vacuum-Assisted Delivery Systems

Product Family Name	Applicable P/N's to be CE Marked
Prism Healthcare® MityVac® / Mystic™ (Vacuum Assist Delivery Devices & Accessories)	10004, 10008, 10020, 10021, 10137, 10500, 10022, 10057, 10058, 10007LP & 10015LP.

Intrauterine Insemination

Product Family Name	Applicable P/N's to be CE Marked
Intrauterine Insemination [IUI] Catheters for Artificial Insemination [Uni-Sem™ and Select Medical's]	Uni-Sem™: 7033 Select Medical's: SM400, SM507, SM610.

Neonatal Care

Product Family Name	Applicable P/N's to be CE Marked
Prism Healthcare® Medical Heat Packs	20418, 20421, & 24401.
Ackrad™ Product Line Extension	INCA®: 025-009, 025-010, 025-011, 025-012, 025-013, 44-0707, 44-0709, 44-0710, 44-0712, 44-0715, 44-2707, 44-2709, 44-2710, 44-2712, 44-2715, 44-8000, 44-8001.
Ackrad™ Product Line Extension	COMFIT™ / TRAKE-fit™ / NEO-fit™ / NEO-prep: 42-1820, 43-1850, 43-1851, 43-1862, 42-2540, 44-8000, 44-8001