



EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions
 102 First Street South
 Kalona, Iowa 52247 United States
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declare under our sole responsibility that the medical imaging accessory product described hereafter...

**Sterile and Non-sterile Drapes / Covers
 as specified in master list ML 000004**

is in conformity with the general safety and performance requirements and provisions of *Council Directive 93/42/EEC* for Medical Devices,

as a *Class IIa* product following *Rule 5 (body orifice invasive, short-term use)* and *Rule 7 (surgically invasive, short-term use)* from *Annex IX of Council Directive 93/42/EEC*,

and is subject to the procedure set out in *Annex II (excluding Section 4) of Directive 93/42/EEC as amended by 2007/47/EC* under the supervision of *Notified Body number 1639, SGS Belgium NV, SGS House-Noorderlaan 87, Antwerp 2030 Belgium*.

Kalona, Iowa USA *December 2019*

European Regulatory Representative:

MPS
 Medical Product Service GmbH
 Borngasse 20
 35619 Braunfels, Germany
 Phone: 49 6442 32370
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			Date: <i>Dec-2019</i>
Person Responsible for Regulatory Compliance (PRRC)			
Date	Rev	Description	Issued By
1 Nov 2019	1	Release new Declaration of Conformity, notified body SGS Belgium	kg

Master List ML 000004

Technical File Number: 000004

Device: Sterile and Non-sterile Drapes/Covers

Part Number:	Description:
610-001	COVER KIT-FLAT CIV-FLEX STERILE 8.9 X 61CM
610-002	COVER KIT-FLAT CIV-FLEX STERILE 14 X 61CM
610-004	COVER KIT-FLAT CIV-FLEX STERILE 17.8 X 61CM
610-005	COVER KIT-FLAT CIV-FLEX STERILE 22.9 X 61CM
610-006	COVER KIT-FLAT CIV-FLEX STERILE 11.9 > 3.8 X 61CM
610-007	COVER-FLAT CIV-FLEX 11.9 > 3.8 X 61CM
610-010	COVER-ROLLED LATEX 3.5 X 20CM
610-011	COVER-ROLLED LATEX 3.5 X 20CM
610-013	COVER KIT-FLAT POLY STERILE 5 X 61CM
610-015	COVER KIT-FLAT POLY STERILE 10.2 X 61CM
610-020	COVER KIT-FLAT POLY STERILE 17.8 X 61CM
610-022	COVER KIT-FLAT POLY STERILE 22.9 X 61CM
610-023	COVER-ACCORDION SURGI POLY STERILE 15.2 > 7.6 X 244CM
610-039	COVER-ROLLED LATEX 2 X 20CM
610-040	COVER-ROLLED LATEX 2.6 X 20CM
610-041	COVER-ROLLED LATEX 4 X 30CM
610-042	COVER KIT-ROLLED LATEX STERILE 4 X 30CM
610-043	COVER KIT-ROLLED LATEX STERILE 5 X 30CM
610-044	COVER KIT-ROLLED LATEX STERILE 8 X 45CM
610-046	COVER KIT-ROLLED LATEX STERILE 10 X 45CM
610-075	COVER-ROLLED LATEX STERILE 2 X 20CM
610-076	COVER-ROLLED LATEX STERILE 2.6 X 20CM
610-1000	COVER KIT-TELE CIV-FLEX STERILE 10.2 X 147 CM
610-101	COVER-ROLLED LATEX 2.6 X 30CM
610-1010	COVER KIT-TELE CIV-FLEX STERILE 17.8 X 147CM
610-1013	COVER KIT-TEE CIV-FLEX STERILE 3.8> 1.7 X 91.4CM
610-1028	COVER KIT-TELE CIV-FLEX 14 X 147CM
610-1029	COVER KIT-TELE CIV-FLEX 10.2 X 147CM
610-1038	COVER KIT-NEOGUARD STERILE 2.6 X 30CM

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Part Number:	Description:
610-1039	COVER KIT NEOGUARD NON-STERILE 2.6 X 30CM
610-1064	COVER KIT-TELE CIV-FLEX STERILE 10.2 X 147CM
610-1072	COVER KIT ACCORDION FOLDED SURGI TIP 3CM NEOGUARD STERILE 15.2 X 244CM
610-1119	COVER KIT TELE CIV-FLEX STERILE 10.2 x 244CM
610-1120	COVER KIT TELE CIV-FLEX STERILE 14 x 244CM
610-1120TR	CIV-Flex Cover 14 x 244cm Tray Ready Non-sterile
610-1121	COVER KIT TELE CIV-FLEX STERILE 17.8 x 244CM
610-1126	COVER KIT-ROLLED NEOGUARD STERILE 2.0 X 30CM
610-1127	COVER KIT-ROLLED NEOGUARD 2.0x30CM
610-1199	COVER KIT-ROLLED LATEX STERILE 3.5 X 20CM
610-1212	COVER KIT-TELE CIV-FLEX STERILE 14 X 30CM
610-1226	COVER KIT-TELE CIV-FLEX STERILE 17.8 X 91.5CM
610-1229	TEE-PED NON LATEX COVER KIT
610-1269	COVER KIT FLAT CIV-FLEX STERILE 14 X 61CM
610-1270	COVER KIT TELE CIV-FLEX STERILE 14 X 91.5CM
610-1271	COVER KIT TELE CIV-FLEX STERILE 14 X 147CM
610-1272	COVER KIT TELE CIV-FLEX STERILE 8.9 X 91.5CM
610-1273	COVER KIT TELE CIV-FLEX STERILE 10.2 X 147CM
610-1302	COVER KIT - FLAT CIV-FLEX STERILE 14X30cm
610-1303	COVER - FLAT CIV-FLEX STERILE 17.8X61CM
610-1304	COVER KIT - CIV-FLEX STERILE TELEFOLD 14x145cm NO GEL
610-1305	COVER KIT TELE-FOLD, FLAT END, CIV-FLEX STERILE 7.4<9.5x30.5CM
610-1309	COVER KIT - TELESCOPICALLY FOLDED CIV-FLEX 17.8x147cm
610-1310	INTUIT Glide Transducer Cover Kit
610-1311	INTUIT Roll Transducer Cover Kit
610-1312	INTUIT SnapFIT Cover Kit
610-1316	Intuit Glide Cover Kit 5.5 x 58"
610-1331	Cover-Rolled Neoguard Sterile 5 to 1.9x32cm
610-1343	CIV-Flex Cover Kit 11.9 x 3.8 x 147cm Sterile

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Part Number:	Description:
610-1347	Intuit Roll Cover Kit 5.5 x 58"
610-1348	Non-sterile 2.6x30 NeoGuard
610-1349	Non-sterile 2.6x30 NeoGuard
610-1391	Sterile CIV-Flex Cover 11.9 tapered to 3.8 x 244cm
610-1600	CIV-Flex Transducer Cover – TEE Cover on Applicator 3.8 tapered to 1.7x122cm Sterile
610-208	COVER KIT-FLAT POLY STERILE 15.3 X 83.8CM
610-212	COVER-ROLLED LATEX STERILE 2 X 30CM
610-213	COVER-ROLLED LATEX STERILE 2.6 X 30CM
610-214	COVER-ROLLED LATEX STERILE 3.5 X 20CM
610-217	COVER KIT-FLAT SURGI POLY STERILE 15.2 > 7.6 X 244CM
610-2289	Intuit Roll Transducer Cover with PeelSafe Advantage
610-2290	Intuit SnapFIT Transducer cover with PeelSafe Advantage
610-2312	Sterile CIV-Flex Cover 14 x 91.5cm with PeelSafe
610-2313	Sterile CIV-Flex Cover 14 x 147cm with PeelSafe
610-2327	Non-Sterile CIV-Flex Cover 2.5 x 36"
610-2328	CIV-Flex Transducer Cover 5.5x96" with PEELSafe
610-2361	CIV-Clear Transducer Cover – CIV-Clear 14x61cm Sterile
610-2362	CIV-Clear Transducer Cover – CIV-Clear 14x91.5cm Sterile
610-2363	CIV-Clear Transducer Cover – CIV-Clear 14x122cm Sterile
610-2364	CIV-Clear Transducer Cover – CIV-Clear 18x91.5cm Sterile
610-2365	CIV-Clear Transducer Cover – CIV-Clear 10.2x122cm Sterile
610-2366	CIV-Clear Transducer Cover – CIV-Clear 10.2x244cm Sterile
610-2367	CIV-Clear Transducer Cover – CIV-Clear 14x122cm Sterile (no gel)
610-2389	CIV-Clear Transducer Cover – CIV-Clear 14x61cm
610-2396	Transducer Cover - CIV-Flex 14x243.8cm
610-249	COVER-ROLLED LATEX 3.5 X 20CM
610-262	COVER-ROLLED LATEX 3.5 X 20CM
610-323	COVER KIT-FLAT CIV-FLEX STERILE 6 X 91.5CM
610-362	COVER-FLAT CIV-FLEX 14 X 61CM

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Part Number:	Description:
610-367	COVER KIT-ACCORDION SURGI POLY STERILE 15.2 > 7.6 X 244CM
610-542	COVER KIT-TELE CIV-FLEX STERILE 14 X 91.5CM
610-542TR	CIV-Flex Cover 14x91.5cm Tray Ready Non-sterile
610-575	COVER KIT-TELE CIV-FLEX STERILE 14 X 147CM
610-575B	COVER KIT-TELE CIV-FLEX STERILE 14 X 147CM
610-575TR	CIV-Flex Cover 14 x 147cm Tray Ready Non-Sterile
610-637	COVER KIT-TELE CIV-FLEX STERILE 8.9 X 91.5CM
610-795	TRANSDUCER COVER - LATEX 3.2 TAPERED to 1.9x32cm
610-797	SURGI-BOOT TRANSDUCER COVER - POLYETHYLENE 15.2x244cm STERILE
610-833	SURGI-TIP TRANSDUCER COVER - POLYETHYLENE 3x15.2x244cm STERILE
610-834	SURGI-TIP TRANSDUCER COVER - POLYETHYLENE 6x20.3x244cm STERILE
610-836	COVER-ROLLED NEOGUARD 2.6 X 30CM
610-838	COVER-ROLLED NEOGUARD 4 X 30CM
610-840	COVER KIT-TEE CIV-FLEX 4.6 > 2.5 X 122CM
610-843	COVER-ROLLED NEOGUARD STERILE 2.6 X 30CM
610-844	COVER-ROLLED NEOGUARD STERILE 4 X 30CM
610-860	COVER-TEE CIV-FLEX 4.6 > 2.5 X 122CM
610-903	COVER-FLAT CIV-FLEX 14 X 30CM
610-933	COVER KIT-TEE CIV-FLEX STERILE 4.6 > 2.5 X 122CM
610-941	COVER KIT-TELE SURGI-TIP LAPAROSCOPIC NEOGUARD STERILE 15.2 X 244 CM
610-973	COVER-CIVFLEX TRANSDUCER COVER NON STERILE
610-985	COVER-ROLLED STERILE LATEX 3.2 TAPERED TO 1.9 X 32CM
610-989	COVER KIT-TELE POLY STERILE 15.2 X 147CM
610-999	COVER KIT-TELE CIV-FLEX STERILE 11.9 > 3.8 X 91.5CM
670-038	CIV-Flex Transducer Cover 10.1 tapered to 2.5 x 30.5cm
676-117	COVER-ROLLED NEOGUARD 2.6X30CM FOR WITH ENDO-PII
H2O-006	Envision Scanning Pad Sterile
H2O-007	Envision Scanning Pad Non-sterile
H2O-008	Envision CIV-Flex Cover Sterile 14x61cm

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Part Number:	Description:
H2O-009	Envision CIV-Flex Cover Sterile 14x91.5cm
H2O-010	Envision CIV-Flex Cover Sterile 14x147cm
H2O-016	Envision Transducer Cover Sterile 14 x 30cm
H2O-018	Envision Transducer Cover Sterile 14 x 244cm
H2O-020	ENVISION TRANSDUCER COVER - CIV-FLEX 14X30CM W/TAPE, STERILE
SH-01	CIV-Flex GUIDE SHEATH
UA0005	COVER-ROLLED LATEX STERILE 2.6 X 30CM
UA0006	COVER-ROLLED STERILE LATEX 3.5 X 20CM
UA0007	COVER KIT-FLAT CIV-FLEX STERILE 14 X 61CM
UA0008	COVER-STERILE 11.9 > 3.8 X 61CM CIV-FLEX
UA0009	COVER KIT-FLAT CIV-FLEX STERILE 8.9 X 61CM
UA0032	COVER-ROLLED LATEX 3.2 TAPERED TO 1.9 X 32CM
UA0037	COVER-ROLLED LATEX 2.6 X 30CM
UA0067	COVER KIT-TELE SURGI-TIP LAPAROSCOPIC NEOGUARD STERILE 15.2 X 244CM
UA0068	COVER-ROLLED NEOGUARD STERILE 2.6 X 30CM
UA0069	COVER-ROLLED STERILE LATEX 3.2 TAPERED TO 1.9 X 32CM
UA0070	COVER KIT-TELE CIV-FLEX STERILE 14 X 91.5CM
UA0071	COVER KIT-TELE CIV-FLEX STERILE 8.9 X 91.5CM
UA0072	COVER KIT-TELE SURGI-TIP NON-LATEX STERILE 9 X 19.7 X 244CM
UA0073	COVER KIT-TELE SURGI-TIP NEOGUARD STERILE 3 X 15.2 X 244CM
UA0074	COVER KIT-TELE SURGI-TIP NEOGUARD STERILE 6X20.3X244CM
UA0075	COVER KIT-TELE SURGI-BOOT NEOGUARD STERILE 15.2 X 244CM
UA0076	COVER KIT-TELE CIV-FLEX STERILE 14 X 147CM
04510947	COVER KIT-FLAT CIV-FLEX STERILE 17.8 X 61 CM
08990418	COVER KIT-ROLLED LATEX 3.2 > 1.9 X 32CM
08990426	COVER KIT-ROLLED LATEX STERILE 3.2 > 1.9 X 32CM W/POLY CORD COVER
11003359	Replacement Kit-Wireless Cover, 14x30cm