



DECLARATION OF CONFORMITY

FULL QUALITY ASSURANCE SYSTEM

Product Name:	Endoscopic Instruments and Accessories: Spare Cap for Endoscope, Spare Cap for Tube, Bone Chisel, Probe Dissector, Trephine, Trephine Protection Tube, Working Tube, Dilator, Trephine Handle, Mallet, Hook, Hook Probe, Ball Probe, Endoscopic Kerrison, Endoscopic Kerrison Handle, Duckling Basket Punch, Suction Punch, Stenosis Kerrison, Scissor Punch, Cupped Forceps, Cup Forceps, Rasp, Micro Cup Forceps, Hook Scissors, Punch, Semi-Flexible Grasper, Grasping Forceps, Rod Forceps, Bone Curette, Guidewire, Driver, Stop Cock	
Intended Use:	The Endoscopic Accessories are used in the manipulation and removal of tissue and bone during spinal endoscopic procedures and minimally invasive surgery.	
Model Numbers:	10-9000, 11-2300, 11-2301, 11-2307, 11-2311, 11-2312, 11-2313, 11-2314, 11-2314L, 11-2315, 11-2315L, 11-2316, 11-2316L, 11-2317, 11-2317L, 11-2318, 11-2319, 11-2320, 11-2321, 11-2322, 11-2323, 11-2334, 11-2335, 11-2337, 11-2909, 11-2910, 11-2911, 11-2912, 11-2912L, 11-2913, 11-2914, 11-2915, 11-2916, 11-2917, 11-2918, 11-2919, 11-2920, 11-2923, 11-2924, 11-2925, 11-2927, 11-2926, 11-2411, 11-2412, 11-2413, 11-2415, 11-2416, 11-2417, 11-2418, 11-2420, 11-2421, 11-3011, 11-3012, 11-2813, 11-2814, 11-2815, 11-2816, 11-2817, 11-2811, 11-2812, 12-1213, 12-1214, 12-1215, 12-1216, 12-1217, 12-1218, 12-1317, 12-1318, 12-1418, 12-1419, 12-1420, 12-1421, 12-2148, 12-2149, 12-2249, 12-1111, 12-1112, 12-1520, 12-1521, 12-1522, 12-1523, 12-1524, 12-1525, 12-1526, 12-1527, 12-1624, 12-1625, 12-1626, 12-1627, 12-1628, 12-1629, 12-1630, 12-1631, 12-1632, 12-1633, 12-1730, 12-1731, 12-1732, 12-1733, 12-1734, 12-1834, 12-1835, 12-1836, 12-1837, 12-1838, 12-1839, 11-2613, 11-2615, 11-2616, 11-2612, 11-2611, 11-2614, 11-2711, 11-2712, 11-2713, 11-2714, 11-2715, 11-2716, 11-2717, 11-2718, 11-2720, 11-2721, 11-2512, 12-1937, 12-1938, 12-1939, 12-1940, 12-1941, 12-1944, 12-1945, 12-1946, 12-1947, 12-1952, 12-1953, 12-1950, 12-1951, 12-1960, 12-1961, 12-2046, 12-2047, 11-2921, 11-2922, 11-2511, 11-2513, 11-2514, 11-3013	
GMDN Code:	Spinal Endoscopic-Access System [32579]	
Device Classification:	I, Rule 6	
Applied Standards:	ISO 10993-1:2009 AAMI / ANSI ST81:2004/(R)2010 EN ISO 15223-1:2016	ISO 13485:2016 EN ISO 14971:2012 EN 1041:2008+A1:2013
Manufacturer:	Elliquence, LLC 2455 Grand Avenue Baldwin, New York 11510 USA	Phone: (516) 277-9000 Fax: (516) 277-9001 Email: quality@elliquence.com
EU Representative:	EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.7299 Email: service@emergogroup.com
Serial Number/Lot Number:		

This declaration of conformity is issued under the sole responsibility of the manufacturer. The object of the declaration described above is in conformity with the relevant Community Harmonization Legislation. I hereby declare that the products specified above meet the requirements set forth in LVFS 2003:11 and Council Directive MDD 93/42/EEC, MDD Annex II (3) and conform to the identified harmonized standards. In addition, the object of the declaration described above is in conformity with RoHS Directive 2011/65/EU (RoHS 2) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. [RoHS]

Alan Ellman, CEO

February 10, 2024

Date