



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

Model Numbers: 11-2300, 11-2301, 11-2311, 11-2312, 11-2313, 11-2314, 11-2315, 11-2316, 11-2317, 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, 11-2913, 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

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

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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 VII (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]

In addition, I ensure and declare that the distributed CE marked product, as mentioned and falling within Class I, meet the provisions of the EC-Directive which apply to it.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned.

Alan Ellman, CEO

April 21, 2020

Date

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