


**STERIS** DECLARATION OF CONFORMITY

<b>Manufacturer Name and Address:</b>	Key Surgical LLC 8101 Wallace Rd. Eden Prairie, MN 55344 USA
<b>Manufacturer Single Registration Number (SRN)</b>	US-MF-000029021
<b>Authorized Representative Name and Address:</b>	Medical Device Safety Service (MDSS) Schiffgraben 41 D-30175 Hannover Germany
<b>Authorized Representative SRN:</b>	<b>SRN: DE-AR-000005430</b>
<b>Basic UDI-DI:</b>	<b>084977100000000000000003M7</b>
<b>Product:</b>	<b>Instrument Protection</b> Applicable SKUs attached
<b>Intended Purpose:</b>	<b>The Instrument Protectors are disposable devices used to protect the tips and edges of surgical instruments when not in use or during instrument sterilization.</b>
<b>Classification:</b>	Class I non-sterile, non-measuring, non-reusable devices according to rule 1 of Annex VIII
<b>Common Specifications Used:</b>	N/A
<b>ISO 13485 Certificate(s) #:</b>	MD 666821
<b>Start of CE Marking:</b>	2021-01-01
<b>Place of Issue:</b>	Key Surgical LLC, Eden Prairie, MN USA
<b>Date of Issue:</b>	2023-09-01
<b>Revision:</b>	1

We herewith declare that this declaration of conformity is issued under the sole responsibility of the Manufacturer and that the above-mentioned product(s) meet the provisions of REGULATION (EU) 2017/745 for Medical Devices (MDR) amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The product has been subjected to conformity assessment procedures according to EU MDR. All supporting documentation is retained on the premises of the manufacturer.

Signed for, and behalf of Key Surgical LLC– See signature page below.

Approvals:			
	<b>Technical</b>		
<b>Signature:</b>	<i>Kristina Siats</i>		
<b>Name:</b>	Kristina Siats		
<b>Title:</b>	Senior Regulatory Affairs Specialist	<b>Date:</b>	2023-09-01
	<b>Regulatory</b>		
<b>Signature:</b>	<i>Steve Deline</i>		
<b>Name:</b>	Steve Deline, MS RAS		
<b>Title:</b>	Senior Manager, Regulatory Affairs & PRRC	<b>Date:</b>	2023-09-01

### List of Applicable SKUs

Item Numbers	
<b>Tip Caps</b> UMDNS: 16-222 GMDN:63247	01460, 01461, 01462, 01463, 01464, 01465, 01466, 01467, 01468, 01472, 01473, 01474, 01475, 01480, 01481, 01482, 01484, 01485, 01486, 01487, 01488, 01489, 01494, 01800, 01801, 01802, 01803, 01804, 01805, 01806, 01807, 01808, 01809, 01810, 01811, 01812, 01813, 01814, 01815, 01816, 01821, 01824, 01826, 01826, 01827, 01828, 01829, 01830, 01831, 01832, 01833, 01834, 01835, 01836, 01837, 01838, 01839, 01840, 01841, 01842, 01843, 01844, 01845, 01846, 01847, 01848, 01856, 01857, 01858, 01859, 01860, 01861, 01865, 01866, 01867, 01868, 01869, 01870, 01871, 01872, 01873, 01874, 01875, 01876, 01877, 01878, 01879, 01884, 01885, 01886, 01887, 01888, 01889, 01890, 01891, 01892,  30000, 30001, 30002, 30002KS, 30003, 30003KS, 30004, 30004KS, 30005, 30006, 30007, 30008, 30008KS, 30009, 30009KS, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 30101, 30102, 30102KS, 30103, 30103KS, 30104, 30105, 30105KS, 30106, 30107, 30108, 30109, 30201, 30202, 30203, 30204, 30205, 30206, 30207, 30208, 30209, 30301, 30302, 30303, 30304, 30305, 30306, 30307, 30308, 30309, 30311, 30312, 30313, 30315, 30325, 30401, 30402, 30403, 30404, 30405, 30406, 30407, 30408, 30409, 30411, 30412, 30413, 30415, 30417, 30418, 30419, 30497, 30498, 30499, 30502, 30506, 30507, 30522, 30523, 30524, 30527, 30528, 30529, 30530, 30601, 30602, 30603, 30604, 30605, 30607, 30650, 30703, 30705, 30709, 30801, 30802, 30803, 30804, 30805, 30806, 30807, 30808, 30809, 30809, 30811, 30812, 30813, 30815, 30817, 30818, 30819, 30901, 30903, 30904, 30905, 30907, 30908, 30909, 30910,  31001, 31002, 31003, 31004, 31005, 31101, 31101, 31102, 31103, 31104, 31105, 31106, 31107, 31108, 31108KS, 31109, 31201, 31202, 31203, 31204, 31205, 31206, 31207, 31208, 31209, 31303, 31305, 31307, 31403, 31405, 31407, 31501, 31502, 31503, 31504, 31505, 31506, 31507, 31508, 31509, 31605, 31606, 31607, 31608, 31609,  32103, 32406, 32408, 32409, 32411, 32413, 32415, 32417, 32420, 32498, 32499,  34295, 34401, 34402, 34403, 34404, 34405, 34406, 34407, 34408, 34409, 34411, 34412, 34413, 34415, 34416, 34417, 34418, 34419, 34496, 34497, 34801, 34802, 34803, 34804, 34805, 34806, 34807, 34808, 34809, 34811, 34812, 34813, 34815,


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	<p>34816, 34817, 34818, 34819, 34820, 34832, 34844, 34850, 34861, 34862, 34894, 34895,</p> <p>36001, 36002, 36003, 36004, 36005, 36006, 36007, 36008, 36009, 36010, 36011,</p> <p>37405, 37406, 37407, 37409, 37411, 37415, 37811, 38003,</p> <p>308100, 30101S, 30902S</p> <p>I30301, I30302, I30303, I30401, I30402, I30403, I30404, I30405, I30406, I30407, I30408, I30409, I30411, I30412, I30413, I30415, I30418, I30602, I30603, I30604, I30605, I30607, I30801, I30802, I30803, I30804, I30805, I30806, I30807, I30808, I30809, I30904, I30908, I31101, I31103, I31104, I31106, I31109, I31201, I31202, I31207, I31209, I31307,</p> <p>TP0911, TP0912, TP0913</p>
<p><b>Tip Protectors</b> GMDN: 63247</p>	<p>01455, 01457, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499</p> <p>CS1010W, CS2025W, CS3050W</p> <p>PC006500, PC006600, PC006700, PC006800</p> <p>PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, PPT002200, PPT004200, PPT006200, PPT008C</p>