


STERIS DECLARATION OF CONFORMITY

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

List of Applicable SKUs

Item Numbers	
Tip Caps UMDNS: 16-222 GMDN:63247	<p>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,</p> <p>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,</p> <p>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,</p> <p>32103, 32406, 32408, 32409, 32411, 32413, 32415, 32417, 32420, 32498, 32499,</p> <p>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,</p>


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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>Tip Protectors 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>