


**STERIS** DECLARATION OF CONFORMITY

<b>Manufacturer Name and Address:</b>	Key Surgical LLC 8101 Wallace Road. Eden Prairie, MN 55344 USA
<b>Manufacturer Single Registration Number (SRN)</b>	US-MF-000029021
<b>Authorized Representative Name and Address:</b>	MDSS GmbH Schiffgraben 41 D-30175 Hannover Germany
<b>Authorized Representative SRN:</b>	DE-AR-000005430
<b>Basic UDI-DI:</b>	<b>084977100000000000000003M7</b>
<b>Product:</b>	<b>Instrument Protection</b> Applicable SKUs attached
<b>Intended Purpose:</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>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>	2024-03-29
<b>Revision:</b>	2

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.

<b>Approvals:</b>			
	<b>Technical, Техническа, Technická, Teknisk, Technisch, Τεχνικά, Reglamentos, Tehniline, Tekninen, Technique, Tehnički, Műszaki, Affari tecnici, Techninès, Tehniskā, Technische, Techniczne, Regulamentação, Reglementare, Technická, Tehnično, Teknisk</b>		
<b>Signature:</b>			
<b>Name:</b>	Kristina Siats		
<b>Title:</b>	Senior Regulatory Affairs Specialist	<b>Date:</b>	2024-03-29
	<b>Regulatory, Регулаторни, Regulace, regulering, Behördlich, Κανονιστικά, técnicos, Regulatorne, Lakisäätien, Réglementation, Regulativni, Szabályozási, Affari regolatori, reguliavimo, Regulatīvā, Regelgeving, Prawne, técnica, tehnică, Regulačná, Regulativni razdelek, Regulatorisk</b>		
<b>Signature:</b>			
<b>Name:</b>	Steve Deline, MS RAS		
<b>Title:</b>	Senior Manager, Regulatory Affairs	<b>Date:</b>	2024-03-29

EN - Instrument Tip Caps BG - Капачки за накрайници за инструменти CS - Krytky nástrojových hrotů DA - Hætter til instrumentspids DE – Instrumentenaufsätze NL - Doppen voor instrumenttips ET - Instrumentide otsakorgid FI - Instrumenttien kärkisuojukset FR - Bouchons pour pointe d'instrument EL - Πώματα άκρων εργαλείων HU - Eszközcsúcs zárókapokok IT - Cappucci per punte di strumenti LV - Instrumentu uzgāju vāciņi LT - Instrumentų antgalių dangteliai NO – Instrument- tupphetter PL - Nasadki końcówki instrument	<b>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,</b>
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# STERIS DECLARATION OF CONFORMITY

<p>PT - Tampas para pontas de instrumentos  RO - Capace pentru vârful instrumentului  ES - Tapones para puntas de instrumentos  SV – Instrumentspetshättor  TR - Alet Uç Başlıkları  UMDNS: 16-222  GMDN:63247</p>	<p>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, 34816, 34817, 34818, 34819, 34820, 34832, 34844, 34850, 34861, 34862, 34894, 34895,  36001, 36002, 36003, 36004, 36005, 36006, 36007, 36008, 36009, 36010, 36011,  37405, 37406, 37407, 37409, 37411, 37415, 37811, 38003, 308100, 30101S, 30902S  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,  TP0911, TP0912, TP0913</p>
<p>EN - Tip Protectors  BG - Предпазители за крайници  CS - Chrániče hrotu  DA – Spidsbeskyttere  DE – Spitzenschutz  NL – Tipbeschermers  ET – Otsakaitsmed  FI – Kärkisuojaukset  FR - Protections d'embout  EL - Προστατευτικά άκρου  HU – Hegyvédők  IT - Protettori per punte  LV - Uzgaļa aizsargi  LT - Antgalio apsaugos  NO – Spissbeskyttere  PL - Ochroniacze końcówki  PT - Protetores de pontas  RO - Protecții pentru vârful  ES - Protectores de puntas  SV – Spetskydd  TR - Uç Koruyucular  GMDN: 63247</p>	<p>01455, 01457,  01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499  CS1010W, CS2025W, CS3050W  PC006500, PC006600, PC006700, PC006800  PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, PPT002200, PPT004200, PPT006200, PPT008C</p>