


**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>0849771000000000000005MB</b>
<b>Product:</b>	<b>Tray Corner Protectors</b> Applicable SKUs attached
<b>Intended Purpose:</b>	To protect sterilization tray corners and sterilization wrap
<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, Techninês, 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 - Tray Corner Protectors BG - Ъглови предпазители за табли CS - Rohové chrániče síta DA - Hjørnebeskyttere til bakke DE - Schalen-Eckenschoner NL - Hoekbeschermers voor tray ET - Kandiku nurgakaitsmed FI - Tarjottimen kulmasuojukset FR - Protections d'angle pour plateau EL - Προστατευτικά γωνιών δίσκου HU - Tálca-sarokvédők IT - Protezioni angolari per vassoio LV - Paplāšu stūru aizsargi LT - Padėklų kampų apsaugos NO - Hjørnebeskyttere for brett PL - Osłony narożników tacy PT - Protetores de quinas de tabuleiros RO - Protecții pentru colțurile tăvii	<b>CS9113, 42006, 42011, 50073</b> <b>42008, 50062, PC001600, 50063, 50064, 50075</b>
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<p>ES - Protectores de esquinas para bandejas  SV - Hörnskydd för kirurgisk bricka  TR - Tepsi Köşe Koruyucuları  UMDNS: 15-907  GMDN: 65133</p>	
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