


**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>0849771000000000000008MH</b>
<b>Product:</b>	<b>Sterilization Wrap</b> Applicable SKUs attached
<b>Intended Purpose:</b>	A microbial barrier sterilization wrap for use in sterile barrier packaging systems which are designed for the sterilization of surgical instruments
<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, Techninés, 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

<b>Item Numbers</b>	
Sterilization Wrap  GMDN:13735	<p>CBPRO075, CBPRO100, CBPRO1012, CBPRO1215, CBPRO1315, CBSDG/TW1315, CBTWO060, CBTWO075, CBTWO090, CBTWO100, CBTWO120, CBTWR120, CBTWRAP060, CBTWRAP075, CBTWRAP090, CBTWRAP100, CBTWRAP1012, CBTWRAP120, CBTWRAP1315, CBTWRAP1315X, CBTWRAP150, CBTWRAP150F3W, CBTWRAP18135, CBTWRAP1815, CBTWRAP5075, CBTWRAPDRY050, CBTWRAPDRY060, CBTWRAPDRY075, CBTWRAPDRY090, CBTWRAPDRY100, CBTWRAPDRY120, CBTWRAPDRY1315X, CBTWRAPDRY140, CBTWY100, CBTWY120</p> <p>CB030, CB050, CB060, CB075, CB090, CB100, CB100DB, CB1012, CB1014, CB120, CB120DB, CB1315, CB1315DB, CB140, CB150, CB1540, CB1715, CB1715DB, CB1815, CB1815DB</p> <p>CBATWRAP120, CBATWRAP140, CBA060, CBA050, CBA075, CBA090, CBA100, CBA120, CBA1415</p> <p>CBUTWRAP100, CBUTWRAP1215, CBUTWRAP1315, CBUTWY120, CBU1014, CBU1014DB, CBU120, CBU1315, CBU150, CBU140</p> <p>CDBC060, CDBC075, CDBC075DB, CDBC090, CDBC100, CDBC1012, CDBC1012DB, CDBC1014, CDBC120, CDBC120DB, CDBC1215, CDBC1215DB, CDBC1315, CDBC1315DB, CDBC140, CDBC150, CDBC150DB, CDBC1815, CDBC1815DB, CDBG120, CDBG140, CDBTWO090, CDBTWR120, CDBTWRAP090, CDBTWRAP100, CDB140, CDB1815, CDB5075,</p> <p>CDGCB060, CDGCB075, CDGCB075DB, CDGCB090, CDGCB100, CDGCB1012DB, CDGCB1015, CDGCB120, CDGCB120DB, CDGCB1215DB, CDGCB1315, CDGCB1315DB, CDGCB1815DB, CDGTWO1215, CDGTWO1315X, CDGTWRAP060, CDGTWRAP075, CDGTWRAP090, CDGTWRAP100, CDGTWRAP100DB, CDGTWRAP1014, CDGTWRAP120,</p>



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	<p>CDGTWRAP120DB, CDGTWRAP1214, CDGTWRAP1215, CDGTWRAP1315, CDGTWRAP150, CDGTWY1315, CDG075, CDG090, CDG100, CDG120, CDG1215, CDG140, CDG150, CDG1815, CDG1315</p> <p>CGCB050, CGCB060, CGCB075, CGCB075DB, CGCB090, CGCB100, CGCB100DB, CGCB1012, CGCB1014, CGCB1014DB, CGCB1075, CGCB1075DB, CGCB1090, CGCB120, CGCB1215, CGCB1215X, CGCB1315, CGCB1315P120, CGCB1315DB, CGCB1315X, CGCB140, CGCB140X, CGCB150, CGCB1715, CGCB1715F4, CGCB1815, CGCB1815P72, CGCB5045, CGCBA120, CGCBU075, CGCBU090, CGCBU100, CGCBU100DB, CGCBU1012, CGCBU1014, CGCBU1090, CGCBU1215, CGCBU1315DB, CGCBU1315X, CGCBU120, CGCBU1815,</p> <p>CGPRO1215, CGPRO1815</p> <p>CGTWO060, CGTWO090, CGTWO1012, CGTWO1012DB, CGTWO1014, CGTWO1014DB, CGTWO1075, CGTWO1075DB, CGTWO1090DB, CGTWO120, CGTWO1215, CGTWO1215DB, CGTWO1215PZDB, CGTWO1315, CGTWO140, CGTWO1715, CGTWO1715DB, CGTWO1815, CGTWO1815DB</p> <p>CGTWR060, CGTWR090DB, CGTWR100, CGTWR100DB, CGTWR1014, CGTWR1090DB, CGTWR1215PZDB, CGTWR1315, CGTWR1315PZDB, CGTWR1715DB, CGTWR1815PZDB</p> <p>CGTWRAP060, CGTWRAP075, CGTWRAP075DB, CGTWRAP090, CGTWRAP090DB, CGTWRAP100, CGTWRAP100DB, CGTWRAP1012, CGTWRAP1012DB, CGTWRAP1014, CGTWRAP1014DB, CGTWRAP1075, CGTWRAP1090, CGTWRAP1090DB, CGTWRAP120, CGTWRAP120DB, CGTWRAP1215, CGTWRAP1215DB, CGTWRAP1215PZDB, CGTWRAP1315, CGTWRAP1315DB, CGTWRAP1315PZ, CGTWRAP1315PZDB, CGTWRAP140, CGTWRAP140DB, CGTWRAP150, CGTWRAP1715DB, CGTWRAP1815, CGTWRAP1815F4, CGTWRAP1815DB, CGTWRAP5075, CGTWRAP5075DB, CGTWRAPDRY060DB, CGTWRAPDRY075, CGTWRAPDRY090, CGTWRAPDRY090DB, CGTWRAPDRY100, CGTWRAPDRY1012, CGTWRAPDRY1014, CGTWRAPDRY1075, CGTWRAPDRY1090, CGTWRAPDRY120, CGTWRAPDRY120DB, CGTWRAPDRY1215, CGTWRAPDRY1315, CGTWRAPDRY1315D, CGTWRAPDRY1315X, CGTWRAPDRY140, CGTWRAPDRY150, CGTWRAPDRY1715, CGTWRAPDRY1815, CGTWRAPDRY1815M, CGTWRAPDRY060</p> <p>CGTWY060, CGTWY075DB, CGTWY090, CGTWY090DB, CGTWY100, CGTWY100DB, CGTWY1012, CGTWY1012DB, CGTWY1090, CGTWY1090DB, CGTWY1215, CGTWY1215PZDB, CGTWY1315, CGTWY1315DB, CGTWY1815,</p> <p>CGWB120, CGWB1315, CGWB1815,</p> <p>CG060, CG075, CG075DB, CG090, CG090P150, CG100, CG100/P150, CG100DB, CG120, CG120DB, CG1215, CG1315, CG140, CG150, CG1715DB, CG1815DB, CG5075,</p> <p>CGPCB100, CGPCB120, CGPCB1715, CGPCB1815, CGPCBU100, CGPCBU1014, CGPCBU1014DB, CGPCBU1090, CGPCBU1215, CGPCBU1315, CGPCBU140, CGPCBU1815, CGPTWO100, CGPTWO1012, CGPTWO1215, CGPTWO1815, CGPTWRAP060, CGPTWRAP060DB, CGPTWRAP075, CGPTWRAP075DB, CGPTWRAP090, CGPTWRAP100, CGPTWRAP1012, CGPTWRAP1075, CGPTWRAP120, CGPTWRAP1215, CGPTWRAP1315, CGPTWRAP150, CGPTWRAP1815, CGPTWY075, CGPTWY100, CGPTWY1315, CGPTWY1815, CGP1315, CGP150,</p> <p>CGXCB075, CGXCB075DB, CGXCB090, CGXCB100, CGXCB100DB, CGXCB1012, CGXCB1012DB, CGXCB1014, CGXCB1090, CGXCB1090DB, CGXCB1215, CGXCB1215DB, CGXCB1315, CGXCB1315P120, CGXCB1315P120DB, CGXCB1715, CGXCB1715DB, CGXCB1815, CGXCB1815DB, CGXCB5075, CGXCB5075DB, CGXCBU060, CGXCBU060DB, CGXCBU100, CGXCBU1012, CGXCBU1014, CGXCBU1014DB, CGXCBU1090, CGXCBU1090DB, CGXCBU1215, CGXCBU1315, CGXCBU1315DB, CGXCBU1815, CGXTWO1012DB, CGXTWO1090DB, CGXTWO1215PZDB, CGXTWO1315, CGXTWR1090DB, CGXTWR1215PZDB, CGXTWR1715DB, CGXTWRAP075DB, CGXTWRAP090, CGXTWRAP090DB, CGXTWRAP100, CGXTWRAP100DB, CGXTWRAP1012, CGXTWRAP1012DB, CGXTWRAP1090DB, CGXTWRAP1215, CGXTWRAP1215PZDB,</p>
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	<p>CGXTWRAP1315, CGXTWRAP1315PZDB, CGXTWRAP1715DB, CGXTWRAP1815, CGXTWRAP1815DB, CGXTWRAP5075, CGXTWRAP5075DB, CGXTWRAPD100DB, CGXTWRAPD1215DB, CGXTWRAPD1315DB, CGXTWRAPDRY100, CGXTWRAPDRY1215,</p> <p>CGXTWRAPDRY1315, CGXTWY090DB, CGXTWY1012DB, CGXTWY1090DB, CGXTWY1215PZDB, CGXTWY1315, CGXTWY1315DB, CGX090, CGX100, CGX100DB, CGX120, CGX1715DB, CGXTWY1215, CGXTWY090, CGXTWY1012, CGXTWR1815</p> <p>REL340GCBU100, REL340GCBU1014, REL340GCBU1215, REL340GCBU1315, RELGRNCB100, RELGRNCB1050, RELGRNCB1315, RELGRNCB140, RELGRNWB1815, RELGRN/CBU100, RELGRN/CBU140,</p> <p>WBTDRY100DB, WBTWO075, WBTWO1012, WBTWO1014, WBTWO1014DB, WBTWO1315, WBTWRAP060, WBTWRAP075, WBTWRAP090, WBTWRAP100, WBTWRAP100DB, WBTWRAP1012, WBTWRAP1014DB, WBTWRAP1075, WBTWRAP1215, WBTWRAP1215DB, WBTWRAP1315, WBTWRAP1815, WBTWRAPDRY060, WBTWRAPDRY090, WBTWRAPDRY100, WBTWRAPDRY120, WBTWRAPDRY1315X, WBTWRAPDRY150, WBTWRAPDRY150F3, WBTWRAPDRY1012, WBTWY090, WBTWY1014, WBTWY1215, WB075, WB090, WB100, WB1014, WB120, WB140,</p> <p>MCCBATWRAP090, MCCBATWRAP100, M-CBATWRAP120</p> <p>CBTDRY075, CBTDRY090, CBTDRY100, CBTDRY060, CBTDRY120</p>
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