


STERIS DECLARATION OF CONFORMITY

Manufacturer Name and Address:	Key Surgical LLC 8101 Wallace Road. Eden Prairie, MN 55344 USA
Manufacturer Single Registration Number (SRN)	US-MF-000029021
Authorized Representative Name and Address:	MDSS GmbH Schiffgraben 41 D-30175 Hannover Germany
Authorized Representative SRN:	DE-AR-000005430
Basic UDI-DI:	0849771000000000000006MD
Product:	Adhesive Remover Applicable SKUs attached
Intended Purpose:	Solution for removing adhesive residue from medical instruments
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:	2024-03-29
Revision:	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.

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

Item Numbers	
EN - Adhesive Remover / Tape Ex BG - Изделие за отстраняване на лепило CS - Odstraňovač lepidla DA - Klæbefjerner DE - Klebstoffentferner NL - Lijmrestenverwijderaar ET - Liimieemaldi FI - Liimanpoistoaine FR - Dissolvant pour adhésif EL - Μέσο αφαίρεσης κόλλας HU - Ragasztóeltávolító IT - Solvente per adesivi LV - Līmvielu noņēmējs LT - Klijų šalinimo įtaisas NO - Limfjerner PL - Środek do usuwania kleju PT - Removedor de adesivo RO - Soluție de îndepărtare a adezivului ES - Removedor de adhesivo SV - Klisterborttagare TR - Yapıştırıcı Çıkarıcı GMDN:64150	02111, BC2001, BC2006