

## Prohlášení o shodě

My výrobce,

Key Surgical LLC  
8101 Wallace Rd.  
Eden Prairie, MN 55344  
USA

garantujeme a prohlašujeme na vlastní zodpovědnost, že následující výrobky, uvedené v tomto seznamu, jsou zdravotnickými prostředky třídy rizika I, nesterilními (dle MDR), neurčenými k opakovanému použití, bez měřicí funkce, splňující ustanovení EU Medical Device Regulation 2017/745 (MDR), příloha IV pro zdravotnické prostředky, jež se na ně vztahují. Tyto zdravotnické prostředky jsou v souladu s nařízením Medical Device Regulation 2017/745, stanovenými pro vydání EU Prohlášení o shodě. Veškerá související dokumentace je uložena v prostorách společnosti.

Product Family Skupina výrobků	Product Tradename Značka výrobku	Item Number Číslo výrobku	Product Code(s)	Basic UDI-DI	Common Specifications Obecná specifikace
Čisticí kartáčky Určení: čištění zdravotnických prostředků	Key Surgical kartáče s bodlinami	BR-1010, BR-1031, BR-1033	UMDNS: 10-502 GMDN: 34878	084977100000000000000001M3	Nejsou k dispozici žádné obecné specifikace stanovené Evropskou Komisí v MDR, které by byly aplikovatelné pro skupinu výrobků Key Surgical uvedenou v tomto prohlášení.  Standardy, které byly identifikovány a uplatněny jsou součástí technické dokumentace.
	Key Surgical kartáčky pro čištění nástrojů a dutých částí nástrojů	26020 26021 26022 26025 26026 26027 26028 26090 26305 26481 26482 09050 09051 09052 09053 09054 09055 09056 09058 09059 09066 09068 09083 09096 09098 09306 09307 09308 09309 09310 09311 09312 09313 09314 09315 09316 09317 09318 09324 09331 09332	UMDNS: 21-134 GMDN: 34878 & 38835		

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		09333			
		09334			
		09335			
		09336			
		09338			
		09339			
		09340			
		09341			
		09342			
		09343			
		09344			
		09345			
		09346			
		09352			
		09353			
		09356			
		09365			
		09366			
		09380			
		09388			
		09499			
		09745			
		09746			
		09747			
		AT-12-062			
		AT-12-062-50			
		AT-12-087			
		AT-12-087-50			
		AT-12-105			
		AT-12-105-50			
		AT-12-118			
		AT-12-118-50			
		AT-12-125			
		AT-12-125-50			
		AT-12-131			
		AT-12-131-50			
		AT-12-158			
		AT-12-158-50			
		AT-12-197			
		AT-12-197-50			
		AT-12-250			
		AT-12-250-50			
		AT-12-276			
		AT-12-276-50			
		AT-12-375			
		AT-12-375-50			
		AT-12-440			
		AT-12-440-50			
		AT-18-062			
		AT-18-062-50			
		AT-18-087			
		AT-18-087-50			
		AT-18-105			
		AT-18-105-50			
		AT-18-118			
		AT-18-118-50			
		AT-18-125			
		AT-18-125-50			
		AT-18-131			
		AT-18-131-50			
		AT-18-158			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		AT-18-158-50			
		AT-18-197			
		AT-18-197-50			
		AT-18-250			
		AT-18-250-50			
		AT-18-276			
		AT-18-276-50			
		AT-18-375			
		AT-18-375-50			
		AT-18-440			
		AT-18-440-50			
		AT-24-062			
		AT-24-062-50			
		AT-24-087			
		AT-24-087-50			
		AT-24-105			
		AT-24-105-50			
		AT-24-118			
		AT-24-118-50			
		AT-24-125			
		AT-24-125-50			
		AT-24-131			
		AT-24-131-50			
		AT-24-158			
		AT-24-158-50			
		AT-24-197			
		AT-24-197-50			
		AT-24-250			
		AT-24-250-50			
		AT-24-276			
		AT-24-276-50			
		AT-24-375			
		AT-24-375-50			
		AT-24-440			
		AT-24-440-50			
		B-2100-50			
		BBR001			
		BBR002			
		BBR003			
		BR-04-003			
		BR-04-003-50			
		BR-04-080			
		BR-06-039-50			
		BR-06-062			
		BR-06-062-50			
		BR-06-079			
		BR-06-079-50			
		BR-06-250			
		BR-06-250-50			
		BR-06-375			
		BR-06-375-50			
		BR-06-500			
		BR-06-500-50			
		BR-07-075			
		BR-07-075-50			
		BR-07-107			
		BR-07-107-50			
		BR-08-039			
		BR-08-039-50			
		BR-08-070			
		BR-08-070-50			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		BR-08-079			
		BR-08-079-50			
		BR-08-087			
		BR-08-087-50			
		BR-08-092			
		BR-08-092-50			
		BR-08-105			
		BR-08-105-50			
		BR-08-118			
		BR-08-118-50			
		BR-08-131			
		BR-08-131-50			
		BR-08-144			
		BR-08-144-50			
		BR-08-158			
		BR-08-158-50			
		BR-08-250			
		BR-08-250-50			
		BR-08-440			
		BR-08-440-50			
		BR-08-630			
		BR-08-630-50			
		BR-12-079			
		BR-12-079-50			
		BR-12-118			
		BR-12-118-50			
		BR-12-158			
		BR-12-158-50			
		BR-12-197			
		BR-12-197-50			
		BR-12-236			
		BR-12-236-50			
		BR-16-197			
		BR-16-197-50			
		BR-16-236			
		BR-16-236-50			
		BR-16-276			
		BR-16-276-50			
		BR-16-393			
		BR-16-393-50			
		BR-16-443			
		BR-16-443-50			
		BR-16-472			
		BR-16-472-50			
		BR-16-591			
		BR-16-591-50			
		BR-16-787			
		BR-16-787-50			
		BR-18-039			
		BR-18-039-50			
		BR-18-062			
		BR-18-062-50			
		BR-18-070			
		BR-18-070-50			
		BR-18-087			
		BR-18-087-50			
		BR-18-105			
		BR-18-105-50			
		BR-18-125			
		BR-18-125-50			
		BR-18-158			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		BR-18-158-50			
		BR-18-197			
		BR-18-197-50			
		BR-18-250			
		BR-18-250-50			
		BR-18-393			
		BR-18-393-50			
		BR-18-591-50			
		BR-18-880-50			
		BR-2300			
		BR-24-070-50			
		BR-24-080-50			
		BR-24-098-50			
		BR-24-197-50			
		BR-24-200-50			
		BR-24-236-50			
		BR-24-276-50			
		BR-24-312-50			
		BR-24-375-50			
		BR-24-393-50			
		BR-24-425-50			
		BR-24-440-50			
		BR-24-443-50			
		BR-24-880-50			
		BR-4199			
		BR-4299			
		BR-4300			
		BR-4310			
		BR-4320			
		BR-4399			
		BR-4499			
		BR-4599			
		BR-4699			
		BR-4799			
		BR-4899			
		BR-4999			
		BR-5099			
		BR-5199C			
		BR-6099			
		BR-8110			
		BR-8110-50			
		BR-8115			
		BR-8115-50			
		BR-8210			
		BR-8210-50			
		BR-8310			
		BR-8310-50			
		BR-8315			
		BR-8315-50			
		BR-8410			
		BR-8410-50			
		BZ-06-2550			
		BZ-06-2550-50			
		BZ-08-125			
		BZ-08-125-50			
		BZ-10-050			
		BZ-10-050-50			
		BZ-12-062			
		BZ-12-062-50			
		BZ-12-087			
		BZ-12-087-50			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		BZ-12-098			
		BZ-12-098-50			
		BZ-12-125			
		BZ-12-125-50			
		BZ-12-158			
		BZ-12-158-50			
		BZ-16-250			
		BZ-16-250-50			
		BZ-18-062			
		BZ-18-062-50			
		BZ-18-079			
		BZ-18-079-50			
		BZ-18-1000			
		BZ-18-1000-50			
		BZ-18-105			
		BZ-18-105-50			
		BZ-18-125			
		BZ-18-125-50			
		BZ-18-131			
		BZ-18-131-50			
		BZ-18-144			
		BZ-18-144-50			
		BZ-18-1543			
		BZ-18-1543-50			
		BZ-18-158			
		BZ-18-158-50			
		BZ-18-197			
		BZ-18-197-50			
		BZ-18-236			
		BZ-18-236-50			
		BZ-18-250			
		BZ-18-250-50			
		BZ-18-312			
		BZ-18-312-50			
		BZ-18-354			
		BZ-18-354-50			
		BZ-18-393			
		BZ-18-393-50			
		BZ-18-433			
		BZ-18-433-50			
		BZ-18-472			
		BZ-18-472-50			
		BZ-24-125			
		BZ-24-125-50			
		FLEX001			
		FLEX002			
		FLEX003			
		FLEX004			
		FLEX005			
		FLEX006			
		FLEX007			
		FLEX007A			
		FLEX007B			
		FLEX011			
		FLEX021			
		FLEX022			
		FLEX023			
		FLEX024			
		FLEX028			
		FLEX033			
		FLEXSAMP			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		FT-12-197 FT-12-197-50 FT-12-250 FT-12-250-50 FT-12-276 FT-12-276-50 FT-12-375 FT-12-375-50 FT-12-440 FT-12-440-50 FT-12-500 FT-12-500-50 FT-18-197 FT-18-197-50 FT-18-250 FT-18-250-50 FT-18-276 FT-18-276-50 FT-18-375 FT-18-375-50 FT-18-440 FT-18-440-50 FT-18-500 FT-18-500-50 FT-24-197 FT-24-197-50 FT-24-250 FT-24-250-50 FT-24-276 FT-24-276-50 FT-24-375 FT-24-375-50 FT-24-440 FT-24-440-50 FT-24-500 FT-24-500-50 H-FLEX001 H-FLEX002 H-FLEX003 H-FLEX004 H-FLEX005 H-FLEX006 H-FLEX007 H-FLEX007A H-FLEX008H H-FLEX009 H-FLEX010 H-FLEX021 H-FLEX022 H-FLEX023 H-FLEX024 H-FLEX025 H-FLEX026 H-FLEX027 H-FLEX033 H-FLEX034 H-FLEX035 H-FLEXSAMP MED100.10 MED100.11 MED100.12			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		MED100.13			
		MED100.14			
		MED100.15			
		MED100.16			
		MED100.17			
		MED100.18			
		MED100.19			
		MED100.20			
		MED100.21			
		MED100.22			
		MED100.23			
		MED100.24			
		MED100.25			
		MED100.26			
		MED100.27			
		MED100.28			
		MED100.29			
		MED100.30			
		MED100.31			
		MED100.32			
		MED100.48			
		MED100.49			
		MED100.52			
		MED100.57			
		MED100.58			
		MED100.59			
		MED100.61			
		MED100.62			
		MJ-370			
		MJ-370C-1			
		PC-100C			
		PC-112C			
		PC-200C			
		PC-212C			
		PC-300P			
		PC-306P			
		PC-312P			
		PC-400P			
		PC-412P			
		PC-503			
		PC-512			
		PC-515			
		PP-16-039			
		PP-16-039-50			
		PP-16-062			
		PP-16-062-50			
		PP-16-087			
		PP-16-087-50			
		PP-16-105			
		PP-16-105-50			
		PP-16-125			
		PP-16-125-50			
		PP-16-158			
		PP-16-158-50			
		PP-18-197			
		PP-18-197-50			
		PP-18-250			
		PP-18-250-50			
		PP-18-393			
		PP-18-393-50			
		PP-18-591			



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		PP-18-591-50 PP-18-750 PP-18-750-50 PP-22-039-50 PP-22-062-50 PP-22-087-50 PP-22-105-50 PP-22-125-50 PP-22-158-50 PP-22-197-50 PP-24-250-50 PT-28-118-50 PT-28-197-50 BR-06-039 PP-22-039 PP-22-062 PP-22-087 PP-22-105 PP-22-125 PP-22-158 PP-22-197 PP-24-250 PT-28-118 PT-28-197			
	Čisticí kartáčky Key Surgical pro zvláštní určení	BR-3044 BR-3045 BR-3047 BR-31-118 BR-31-197 BR-31-276 BR-3201 BR-3201-50 BR-4140			
	Kartáčky pro čištění sterilizátoru	BR-4000, BR-5000, BR-5200, BR-5400, BR-5450, BR-5455, BR-5500, BR-5600			
	Čisticí kartáčky Key Surgical typu kartáček na zuby	D-2100BN D-2100BN-50 D-2100SN D-2100SN-50 N-2100 N-2100-50 N-2121 N-2121-50 N-2221-50 N-2000-3 N-3000-3 S-2100 S-2100-50 S-2121-50 S-2131 S-2131-50 S-2300 S-2300-50 UB-2100 UD-2100SN UN-2100 UN-2100-50 UN-2121-50 US-2100			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		US-2100-50 US-2300			
	Kartáčky Key Surgical pro čištění endoskopů	26022, 26020, 26021, 26482, 26025, 26028, 26481, 26027, 26090, 26305, 26026, 09356, 09353, 09352, BR-075-18 BR-075-18-50 BR-075-24 BR-075-24-50 BR-075-32 BR-075-32-50 BR-075-42 BR-075-42-50 BR-075-99 BR-100-18 BR-100-18-50 BR-100-24 BR-100-24-50 BR-100-32 BR-100-32-50 BR-100-42 BR-100-42-50 BR-100-99, BR-150-18 BR-150-18-50 BR-150-24 BR-150-24-50 BR-150-32 BR-150-32-50 BR-150-42 BR-150-42-50 BR-150-99 BR-200-18 BR-200-18-50 BR-200-24 BR-200-24-50 BR-200-32 BR-200-32-50 BR-200-42 BR-200-42-50 BR-200-99 BR-3030 BR-3030-50 BR-3035 BR-3035-50 BR-3040 BR-3040-50 BR-3202 BR-3202-50 BR-3299 BR-3300 BR-3305 BR-3307 BR-3308 BR-3308-50 BR-3309 BR-3309-50 BR-3310 BR-3310-50			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		BR-3320 BR-3320-50 BR-3330 BR-3330-50 BR-3340 BR-3340-50 BR-3399 BR-3410 BR-3410-50 BR-3420 BR-3420-50 BR-3701 BR-3702 BR-3703 BR-3711-100 BR-3711-50 BR-3799-50			
	Key Surgical čisticí houby na endoskopy	ES-50	UMDNS: 21- 134 GMDN: 34878		
Irigační kanyly  Účel použití: irigace ran	Key Surgical kanyly (nesterilní)	05001, 05003, 05005, 05007, 05009	UMDNS: 15- 206 GMDN: 62389	08497710000000000000002M5	
Ochranné krytky na nástroje  Účel použití: k ochraně a krytí koncovek zdravotnických nástrojů	Key Surgical  ochranné krytky na špičky nástrojů	3-48-32, 3-48-44, 3-06- 01, 01800, 3-06-02, I3- 06-02, 01801, 3-06-03, I3-06-03, 01802, 3-06- 04, I3-06-04, 01803, 3- 06-05, I3-06-05, 01804, 3-06-07, I3-06- 07, 01805, 3-11-01, I3- 11-01, 1826, 3-11-02, 01827, 3-11-03, I3-11- 03, 01828, 3-11-04, I3- 11-04, 01829, 3-11-05, 01830, 3-11-06, I3-11- 06, 01831, 3-11-07, 01832, 3-11-08, 01833, 3-11-09, I3-11-09, 01834, 3-12-01, I3-12- 01, 01838, 3-12-02, I3- 12-02, 01839, 3-12-03, 01840, 3-12-04, 01841, 3-12-05, 01842, 3-12- 06, 01843, 3-12-07, I3- 12-07, 01844, 3-12-08, 01845, 3-12-09, I3-12- 09, 01846, 3-13-03, 01835, 3-13-05, 01836, 3-13-07, I3-13-07, 01837, 3-14-03, 01847, 3-14-05, 01848, 3-14- 07, 3-48-20, 3-07-03, 3-07-05, 3-07-09, 01856, 01857, 01858,	UMDNS: 16- 222 GMDN: 43387		

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		01859, 01860, 3-10-01, 3-10-02, 3-10-03, 3-10-04, 3-10-05, 3-01-01S, 3-03-25, 3-04-97, 3-04-98, 3-04-99, 3-05-02, 3-05-06, 3-05-07, 3-05-22, 3-05-23, 3-05-24, 3-05-27, 3-05-28, 3-05-29, 3-05-30, 3-09-03, 01814, 3-09-04, 13-09-04, 01815, 3-09-05, 01816, 3-09-07, 3-09-08, 13-09-08, 01472, 01473, 3-09-09, 01474, 01475, 01494, 3-09-10, 3-24-98, 3-24-99, 3-48-50, 3-80-03, 3-60-01, 3-60-02, 3-60-03, 3-60-04, 3-60-05, 3-60-06, 3-60-07, 3-60-08, 3-60-09, 3-60-10, 3-60-11, 01471, 01476, 01477, 01469, 01470, 01478, 01479, 01492, 01496, 01499, 3-01-01, 01865, 3-01-02, 01890, 3-01-03, 01866, 3-01-04, 01867, 3-01-05, 01891, 3-01-06, 01892, 3-02-01, 01893, 01876, 3-02-02, 3-02-03, 01877, 3-02-04, 01878, 3-02-06, 3-03-01, 01871, 3-03-02, 01872, 3-03-03, 01873, 3-03-04, 01874, 3-03-05, 01875, 3-03-06, 3-04-01, 01484, 3-04-02, 01485, 3-04-03, 01486, 3-04-04, 01487, 3-04-05, 01488, 3-04-06, 01489, 3-08-01, 01460, 3-08-02, 01461, 3-08-03, 01462, 3-08-04, 01463, 3-08-05, 01464, 3-08-06, 01465, 3-09-01, 3-09-02S, 3-15-01, 01868, 3-15-02, 01869, 3-15-03, 01870, 3-15-04, 01884, 3-15-05, 01885, 3-15-06, 01886, 3-21-03, 3-24-06, 3-24-20, , 3-42-95, 3-44-01, 3-44-02, 3-44-03, 3-44-04, 3-44-05, 3-44-06, 3-44-96, 3-44-97, 3-48-01,, 3-48-02, 3-48-03, 3-48-04, 3-48-05, 3-48-06, ,3-48-61, 3-48-62, 3-48-94, 3-48-95, 3-74-05, 3-74-06, 13-03-01, 13-03-02, 13-		0849771000000000000003M7	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		03-03, I3-04-01, I3-04-02, I3-04-03, I3-04-04, I3-04-05, I3-04-06, I3-08-01, I3-08-02, I3-08-03, I3-08-04, I3-08-05, I3-08-06, 3-03-11, 3-03-12, 3-03-13, 3-03-15, 3-04-11, 01806, 3-04-12, 01807, 3-04-13, 01808, 01809, 3-04-17, 01811, 3-04-18, 01812, 3-04-19, 01813, 3-08-11, 3-08-12, 3-08-13, 3-08-15, 3-08-17, 3-08-18, 3-08-19, 3-24-11, 3-24-13, 3-24-15, 3-24-17, 3-44-11, 3-44-12, 3-44-13, 3-44-15, 3-44-16, 3-44-17, 3-44-18, 3-44-19, 3-48-11, 3-48-12, 3-48-13, 3-48-15, 3-48-16, 3-48-17, 3-48-18, 3-48-19, 3-74-11, 3-74-15, 3-78-11, I3-04-11, I3-04-12, I3-04-13, I3-04-15, I3-04-18, 3-04-07, 01480, 3-04-08, 01481, 3-04-09, 01482, 01810, 3-08-07, 01466, 3-08-08, 01467, 3-08-09, 01468, 3-15-07, 01887, 3-15-08, 01888, 3-15-09, 01889, 3-24-07, 3-24-08, 3-24-09, 3-44-07, 3-44-08, 3-44-09, 3-48-07, 3-48-08, 3-48-09, 3-74-07, 3-74-09, I3-04-07, I3-04-08, I3-04-09, I3-08-07, I3-08-08, I3-08-09, 3-01-07, 3-01-08, 01818, 01824, 3-01-09, 3-02-07, 01879, 3-02-08, 01880, 3-02-09, 01881, 3-03-07, 3-03-08, 3-03-09, 3-16-05, 3-16-06, 3-16-07, 01820, 01817, 3-16-08, 01821, 3-16-09, 01822, 01819, 01825, 30000, 30001, 30002, 30003, 30004, 30005, 30006, 30007, 30008, 30009, 30010, 30012, 30013, 30014, 30015, 30016, 30017, 01850, 01851, 01852, 01853, 01854, TP-09-11, TP-09-12, TP-09-13			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
Ochranné krytky na K-dráty a kolíky  Účel použití: ochrana K-drátů a kolíků	Key Surgical  ochranné krytky na špičky nástrojů	PPT001, PPT002, PPT003, PPT004, PPT005, PPT006, PPT007C, CS-1010W, CS-2025W, CS-3050W H-PPT001 H-PPT002 H-PPT003 H-PPT004 H-PPT005 H-PPT006 H-PPT007C H-PPT008C PC006500 PC006600 PC006700 PC006800 PPT002/200 PPT004/200 PPT008C 01455 01457			
	Key Surgical ochranné krytky na K-dráty a Steinmannovy kolíky (nesterilní)	C-028NS, C-035NS, C-045NS, C-054NS, C-062NS, C-078NS, C-093NS, C-109NS, C-125NS, C-141NS, C-156NS, C-188NS			
Instrumentační sterilizační tácy  Účel použití: Ochrana nástrojů při čištění, sterilizaci a skladování	Key Surgical plastové sterilizační tácy	PST-0100SB, PST-1100SB, PST-2100SB, PST-3100SB, PST-3200SB, PST-3200SBC-1, PST-3300SB, PST-4200SB	UMDNS:12-143 GMDN:12143	084977100000000000000004M9	
	Key Surgical silikonové ježky	FM-1810			
	Key Surgical síta	08132, 08434, 08435, 08580, 08581, 08761, 08762, 08763, 08772, 08773, 08774, 08776, 08799, 08875, 08896, 08897, 08898, 08899, 08900, 08901, 08902, 08903, 08904, 08905,			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		08906, 08907, 08908, 08909, 08910, 08911, 08912, 08931, 08935, 08936, 08948, 08950, 08951, 08957, 08991, MT-5500, MT-5600, MT-5650, MT-5700, MT-5800, MT-5900, MT-6020, MT-7100, MT-7200, MT-7300, MT-8005, MT-8050, MT-8500, MT-9000, MT-9001, MT-9010, MT-9100, MT-9101, MT-9110, MT-9210, MT-9521, BELBSK116, BELBSK117, BELTRY010, BELTRY013, BSK316, BSK316H, BSK317, BSK317H, BSK318, BSK318H, BSK580X330X75, BSK600X140X50, DIV116, DIV116/4, NIC001R, NIC002, NIC003, NIC003DEEP, NIC004DEEP, NIC004DEEPSJ			
	Key Surgical síta a koše pro endoskopy	SB-1210, SB-4210, SB-4610, SB-6520			
Key Surgical chrániče rohů na sítěch  Účel použití: chrániče na ostré rohy sterilizačních táců a sít	Key Surgical chrániče rohů na sítěch	42006, 42007, 42008, 42010, 42011, 50062, 50073, H-CC001, H-CC002, H-CC003, PC001600, CC001, CC002, CS-9113, CS-9125C	UMDNS: 15-907 GMDN: 63494	084977100000000000000005MB	
Odstraňovač zbytků lepidel  Účel použití: řešení pro	Odstraňovač zbytků lepidel	02111	GMDN:64150	084977100000000000000006MD	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
odstranění zbytků lepidel ze zdravotnických nástrojů					
Horkovzdušná fólie  Účel použití: určeno pro horkovzdušnou sterilizaci	Key Surgical horkovzdušná fólie	36202, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209	UMDNS: GMDN: 13735	0849771000000000000007MF	
Sterilizační netkaná textilie  Účel použití: sterilizační obal	Sterilizační netkaná textilie	CB/PRO075 CB/PRO100 CB/PRO1012 CB/PRO1215 CB/PRO1315 CB/SDG/TW1315 CB/TWO060 CB/TWO075 CB/TWO090 CB/TWO100 CB/TWO120 CB/TWR120 CB/TWRAP060 CB/TWRAP075 CB/TWRAP090 CB/TWRAP100 CB/TWRAP1012 CB/TWRAP120 CB/TWRAP1315 CB/TWRAP1315X CB/TWRAP150 CB/TWRAP150F3W CB/TWRAP18135 CB/TWRAP1815 CB/TWRAP5075 CB/TWRAPDRY050 CB/TWRAPDRY060 CB/TWRAPDRY075 CB/TWRAPDRY090 CB/TWRAPDRY100 CB/TWRAPDRY120 CB/TWRAPDRY1315X CB/TWRAPDRY140 CB/TWY100 CB/TWY120 CB030 CB050 CB060 CB075 CB090 CB100 CB100DB CB1012 CB1014 CB120 CB120DB CB1315	UMDNS: GMDN: 13735	0849771000000000000008MH	



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CB1315DB CB140 CB150 CB1540 CB1715 CB1715DB CB1815 CB1815DB CBA/TWRAP120 CBA/TWRAP140 CBA050 CBA075 CBA090 CBA100 CBA120 CBA1415 CBU/TWRAP100 CBU/TWRAP1215 CBU/TWRAP1315 CBU/TWY120 CBU1014 CBU1014DB CBU120 CBU1315 CBU150 CDB/CG060 CDB/CG075 CDB/CG075DB CDB/CG090 CDB/CG100 CDB/CG1012 CDB/CG1012DB CDB/CG1014 CDB/CG120 CDB/CG120DB CDB/CG1215 CDB/CG1215DB CDB/CG1315 CDB/CG1315DB CDB/CG140 CDB/CG150 CDB/CG150DB CDB/CG1815 CDB/CG1815DB CDB/GC120 CDB/GC140 CDB/TWO090 CDB/TWR120 CDB/TWRAP090 CDB/TWRAP100 CDB060 CDB075 CDB090 CDB100 CDB1012 CDB1014 CDB120 CDB1315 CDB140 CDB150 CDB1815			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CDB5075 CDG/CB060 CDG/CB075 CDG/CB075DB CDG/CB090 CDG/CB100 CDG/CB1012DB CDG/CB1015 CDG/CB120 CDG/CB120DB CDG/CB1215DB CDG/CB1315 CDG/CB1315DB CDG/CB1815DB CDG/TWO1215 CDG/TWO1315X CDG/TWRAP060 CDG/TWRAP075 CDG/TWRAP090 CDG/TWRAP100 CDG/TWRAP100DB CDG/TWRAP1014 CDG/TWRAP120 CDG/TWRAP120DB CDG/TWRAP1214 CDG/TWRAP1215 CDG/TWRAP1315 CDG/TWRAP150 CDG/TWY1315 CDG075 CDG090 CDG100 CDG120 CDG1215 CDG140 CDG150 CDG1815 CG/CB050 CG/CB060 CG/CB075 CG/CB075DB CG/CB090 CG/CB100 CG/CB100DB CG/CB1012 CG/CB1014 CG/CB1014DB CG/CB1075 CG/CB1075DB CG/CB1090 CG/CB120 CG/CB1215 CG/CB1215X CG/CB1315 CG/CB1315/P120 CG/CB1315DB CG/CB1315X CG/CB140 CG/CB140X CG/CB150 CG/CB1715			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CG/CB1715/F4 CG/CB1815 CG/CB1815/P72 CG/CB5045 CG/CBA120 CG/CBU075 CG/CBU090 CG/CBU100 CG/CBU100DB CG/CBU1012 CG/CBU1014 CG/CBU1090 CG/CBU1215 CG/CBU1315DB CG/CBU1315X CG/PRO1215 CG/PRO1815 CG/TWO060 CG/TWO090 CG/TWO1012 CG/TWO1012DB CG/TWO1014 CG/TWO1014DB CG/TWO1075 CG/TWO1075DB CG/TWO1090DB CG/TWO120 CG/TWO1215 CG/TWO1215DB CG/TWO1215PZDB CG/TWO1315 CG/TWO140 CG/TWO1715 CG/TWO1715DB CG/TWO1815 CG/TWO1815DB CG/TWR060 CG/TWR090DB CG/TWR100 CG/TWR100DB CG/TWR1014 CG/TWR1090DB CG/TWR1215PZDB CG/TWR1315 CG/TWR1315PZDB CG/TWR1715DB CG/TWR1815PZDB CG/TWRAP060 CG/TWRAP075 CG/TWRAP075DB CG/TWRAP090 CG/TWRAP090DB CG/TWRAP100 CG/TWRAP100DB CG/TWRAP1012 CG/TWRAP1012DB CG/TWRAP1014 CG/TWRAP1014DB CG/TWRAP1075 CG/TWRAP1090 CG/TWRAP1090DB			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CG/TWRAP120 CG/TWRAP120DB CG/TWRAP1215 CG/TWRAP1215DB CG/TWRAP1215PZDB CG/TWRAP1315 CG/TWRAP1315DB CG/TWRAP1315PZ CG/TWRAP1315PZDB CG/TWRAP140 CG/TWRAP140DB CG/TWRAP150 CG/TWRAP1715DB CG/TWRAP1815 CG/TWRAP1815/F4 CG/TWRAP1815DB CG/TWRAP5075 CG/TWRAP5075DB CG/TWRAPDRY060DB CG/TWRAPDRY075 CG/TWRAPDRY090 CG/TWRAPDRY090DB CG/TWRAPDRY100 CG/TWRAPDRY1012 CG/TWRAPDRY1014 CG/TWRAPDRY1075 CG/TWRAPDRY1090 CG/TWRAPDRY120 CG/TWRAPDRY120DB CG/TWRAPDRY1215 CG/TWRAPDRY1315 CG/TWRAPDRY1315D CG/TWRAPDRY1315X CG/TWRAPDRY140 CG/TWRAPDRY150 CG/TWRAPDRY1715 CG/TWRAPDRY1815 CG/TWRAPDRY1815M CG/TWY060 CG/TWY075DB CG/TWY090 CG/TWY090DB CG/TWY100 CG/TWY100DB CG/TWY1012 CG/TWY1012DB CG/TWY1090 CG/TWY1090DB CG/TWY1215 CG/TWY1215PZDB CG/TWY1315 CG/TWY1315DB CG/TWY1815 CG/WB120 CG/WB1315 CG/WB1815 CG060 CG075 CG075DB CG090 CG090/P150			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CG100 CG100/P150 CG100DB CG120 CG120DB CG1215 CG1315 CG140 CG150 CG1715DB CG1815DB CG5075 CGA/CBA050P100 CGA/CBA060P100 CGA/CBA075P100 CGA/CBA5075P100 CGP/CB100 CGP/CB120 CGP/CB1715 CGP/CB1815 CGP/CBU100 CGP/CBU1014 CGP/CBU1014DB CGP/CBU1090 CGP/CBU1215 CGP/CBU1315 CGP/CBU140 CGP/CBU1815 CGP/TWO100 CGP/TWO1012 CGP/TWO1215 CGP/TWO1815 CGP/TWRAP060 CGP/TWRAP060DB CGP/TWRAP075 CGP/TWRAP075DB CGP/TWRAP090 CGP/TWRAP100 CGP/TWRAP1012 CGP/TWRAP1075 CGP/TWRAP120 CGP/TWRAP1215 CGP/TWRAP1315 CGP/TWRAP150 CGP/TWRAP1815 CGP/TWY075 CGP/TWY100 CGP/TWY1315 CGP/TWY1815 CGP1315 CGP150 CGX/CB075 CGX/CB075DB CGX/CB090 CGX/CB100 CGX/CB100DB CGX/CB1012 CGX/CB1012DB CGX/CB1014 CGX/CB1090 CGX/CB1090DB			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CGX/CB1215 CGX/CB1215DB CGX/CB1315 CGX/CB1315/P120 CGX/CB1315P120DB CGX/CB1715 CGX/CB1715DB CGX/CB1815 CGX/CB1815DB CGX/CB5075 CGX/CB5075DB CGX/CBU060 CGX/CBU060DB CGX/CBU100 CGX/CBU1012 CGX/CBU1014 CGX/CBU1014DB CGX/CBU1090 CGX/CBU1090DB CGX/CBU1215 CGX/CBU1315 CGX/CBU1315DB CGX/CBU1815 CGX/TWO1012DB CGX/TWO1090DB CGX/TWO1215PZDB CGX/TWO1315 CGX/TWR1090DB CGX/TWR1215PZDB CGX/TWR1715DB CGX/TWRAP075DB CGX/TWRAP090 CGX/TWRAP090DB CGX/TWRAP100 CGX/TWRAP100DB CGX/TWRAP1012 CGX/TWRAP1012DB CGX/TWRAP1090DB CGX/TWRAP1215 CGX/TWRAP1215PZDB CGX/TWRAP1315 CGX/TWRAP1315PZDB CGX/TWRAP1715DB CGX/TWRAP1815 CGX/TWRAP1815DB CGX/TWRAP5075 CGX/TWRAP5075DB CGX/TWRAPD100DB CGX/TWRAPD1215DB CGX/TWRAPD1315DB CGX/TWRAPDRY100 CGX/TWRAPDRY1215 CGX/TWRAPDRY1315 CGX/TWY090DB CGX/TWY1012DB CGX/TWY1090DB CGX/TWY1215PZDB CGX/TWY1315 CGX/TWY1315DB CGX090 CGX100			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CGX100DB CGX120 CGX1715DB FILT003G FILT004 MC-CBA/TWRAP090 MC-CBA/TWRAP100 MC-CBA/TWRAP120 REL340G/CBU100 REL340G/CBU1014 REL340G/CBU1215 REL340G/CBU1315 RELGRN/CB100 RELGRN/CB1050 RELGRN/CB1315 RELGRN/CB140 RELGRN/WB1815 WB/TDRY100DB WB/TWO075 WB/TWO1012 WB/TWO1014 WB/TWO1014DB WB/TWO1315 WB/TWRAP060 WB/TWRAP075 WB/TWRAP090 WB/TWRAP100 WB/TWRAP100DB WB/TWRAP1012 WB/TWRAP1014DB WB/TWRAP1075 WB/TWRAP1215 WB/TWRAP1215DB WB/TWRAP1315 WB/TWRAP1815 WB/TWRAPDRY060 WB/TWRAPDRY090 WB/TWRAPDRY100 WB/TWRAPDRY120 WB/TWRAPDRY1315X WB/TWRAPDRY150 WB/TWRAPDRY150F3 WB/TWY090 WB/TWY1014 WB/TWY1215 WB075 WB090 WB100 WB1014 WB120 WB140			
Transportní netkaná textilie  Účel použití: transportní ochranný obal	Transportní netkaná textilie	PC000100 PC000200 PC000300 PC000500 PC000600 PC00900 PRO060 PRO090 TDRY075 TDRY090	GMDN: 13735	0849771000000000000009MK	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		TDRY100			
		TDRY120			
		TDRY3024			
		TDRYPACK1012			
		TDRYPACK1815			
		TWO050			
		TWO060			
		TWO075			
		TWO075DB			
		TWO090			
		TWO100			
		TWO1012			
		TWO1012DB			
		TWO1014			
		TWO120			
		TWO1215			
		TWO1215DB			
		TWO1315			
		TWO140			
		TWO140DB			
		TWO150			
		TWO150DB			
		TWO1715DB			
		TWO1815			
		TWO5075			
		TWR060			
		TWR075			
		TWR075DB			
		TWR090			
		TWR100			
		TWR100DB			
		TWR1012DB			
		TWR1014			
		TWR1090DB			
		TWR120			
		TWR1215DB			
		TWR1315			
		TWR140			
		TWR150			
		TWR1715DB			
		TWR1815			
		TWR5075DB			
		TWRAP050			
		TWRAP060			
		TWRAP075			
		TWRAP075DB			
		TWRAP090			
		TWRAP100			
		TWRAP100DB			
		TWRAP1012			
		TWRAP1012DB			
		TWRAP1014			
		TWRAP1090DB			
		TWRAP120			
		TWRAP1215			
		TWRAP1215DB			
		TWRAP1315			
		TWRAP1315DB			
		TWRAP140			
		TWRAP140DB			
		TWRAP150			



Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		TWRAP150DB TWRAP1715 TWRAP1715DB TWRAP1815 TWRAP1815DB TWRAP5090 TWRAP5390 TWRAP7537 TWRAP75375 TWRAPDRY050 TWRAPDRY060 TWRAPDRY075 TWRAPDRY090 TWRAPDRY100 TWRAPDRY1012 TWRAPDRY1014 TWRAPDRY120 TWRAPDRY1315 TWRAPDRY140 TWRAPDRY1815 TWRAPDRY3015 TWRAPDRY3015SGL TWRAPDRY5075 TWRAPDRY7560 TWRAPDRYOFFCUT TWY075 TWY075DB TWY090 TWY100 TWY100DB TWY1012 TWY1014 TWY120 TWY1215 TWY1215DB TWY1315 TWY1315DB TWY140 TWY1715 TWY1715DB TWY1815 CDBAG002G DGM-TCOVER4270 H-THCOVER001 H-THCOVER002 H-THCOVER003 H-THOCOVER001 H-THOCOVER002 H-THOCOVER003 H-THRCOVER001 H-THRCOVER002 H-THRCOVER003 H-THYCOVER001 H-THYCOVER002 H-THYCOVER003 PC000700 PC000800 PC000900 PC011500 PC011600 TCOVER001			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		TCOVER002 TCOVER003 TCOVER007 TCOVER008 TCOVERDRY001 TCOVERDRY002 TCOVERDRY003 TCOVER-RED001 TCOVER-RED002 TCOVER-RED003 TCOVER-YELL001 TCOVER-YELL002 TCOVER-YELL003			
Transportní netkaná textilie  Účel použití: transportní ochranný obal	Transportní netkaná textilie	DRYMAT001 DRYMAT002 DRYMAT003 DRYMAT003P500 DRYMAT004 DRYMAT005 DRYMAT006 DRYMAT007 DRYMAT008 DRYMAT009 DRYMAT010 DRYMAT011 DRYMAT013 DRYMAT018 DRYMATGRN001 DRYMATGRN002 DRYMATGRN003 H-DRYMAT001 H-DRYMAT002 H-DRYMAT003 H-DRYMAT004 H-DRYMAT011 H-DRYMAT018 H-DRYMATGRN001 H-DRYMATGRN002 H-DRYMATGRN003 H-MAT001 H-MAT002 H-MAT003 MAT001 MAT002 MAT003 MAT004 MAT005 MAT007 PC002300 PC002400	GMDN: 13735		
Kontejnerové filtry  Účel použití: spotřební materiál pro sterilizační kontejnery	Kontejnerové filtry	01140 01141 01142 01143 01144 01145 01148 01149 01152 01153 01157	GMDN: 60909	0849771000000000000010M4	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		01158 01167 01168 01181 01183 01186 01188 01189 01194 01196 01198 01300 01304 01306 01312 01314 01315 01317 01318 01319 01321 01322 01323 01327 01330 01331 01332 01346 01347 01348 01350 01355 01356 01363 01365 01366 01367 01368 01369 01373 04111 1070020 26510 27320 27330 27340 27350 27360 55-291-01-04 61140 71140 71141 71194 91140			
Absorpční papír Účel použití: při sterilizaci zdravotnických prostředků	Absorpční papír	49937 49938 50110 51448 1136011 1137011 CBL003	GMDN:61664	0849771000000000000011M6	

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		CBL300X300H			
		CBL350X350			
		CBL400X400			
		CBL400X600			
		CBL500X700			
		CBL580X350			
		H-CBL001			
		H-CBL002			
		H-CBL003			
		H-TLC004			
		H-TLC005			
		H-TLC006			
		H-TLC007			
		H-TLC008			
		H-TLC009			
		H-TLC010			
		H-TLC011			
		H-TLC012			
		H-TLC013			
		H-TLC078			
		H-TLC109			
		H-TLC110			
		H-TLC111			
		H-TLC119			
		H-TLC213			
		H-TLC214			
		H-TLC215			
		LIB1328			
		LIB250X320			
		LIB300X360			
		LIB300X500			
		LIB3025			
		LIB3050			
		LIB400X500			
		LINH3020			
		LINH3041			
		LINH4555			
		MILB002			
		MILB003			
		MILB004			
		MILB005			
		MILB006			
		MILB007			
		MILB008			
		MILB009			
		MILB011			
		MILB012			
		MILB016			
		MILB017			
		MILB019			
		MILB020			
		MILB021			
		MILB022			
		MILB025			
		MILB027			
		MILB029			
		MILB056			
		MILB120X250			
		MILB130X230			
		MILB170X270			
		MILB250X300			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		MILB300X400 MILB305X450 MILB350x450 MILB375X600 MILB450X650 MILB500X900 M-MILB300X600 M-MILB400X300 M-MILB500X400 M-TLC004 M-TLC007 M-TLC008 M-TLC010 M-TLC036 M-TLC045 M-TLC051 PC002100 PC002200 PC008800 PC008900 PC009000 PC009100 PC009200 PC009400 PC009800 PC009900 PC010000 PC010200 PC010400 PC010700 PC010800 PC011200 PC011300 PC011400 PC011700 PC011800 PC013300 PC013600 TL-101-200 TL-202-500 TL-203-500 TL-204-500 TLC001 TLC002 TLC004 TLC005 TLC006 TLC007 TLC008 TLC009 TLC010 TLC011 TLC012 TLC013 TLC014 TLC017 TLC018 TLC019 TLC020 TLC022 TLC023			

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		TLC024 TLC027 TLC029 TLC030 TLC031 TLC034 TLC036 TLC045 TLC051 TLC052 TLC055 TLC060 TLC066 TLC069 TLC071 TLC072 TLC078 TLC079 TLC081 TLC085 TLC086 TLC087 TLC095 TLC096 TLC098 TLC100 TLC102 TLC103 TLC104 TLC107 TLC108 TLC109 TLC110 TLC114 TLC115 TLC116 TLC120 TLC122 TLC220 TLC3044 TLC340 TLC3535 TLC3548 TLC420X330 TLC450 TLC5060 TLC520X360 TLC540X250 TLP-012-018 TLP-020-025			
	Absorpční a ochranný arch	H-CT005 H-SOK001SS H-SOK002SS H-SOK003SS H-SOK006SS H-SOK008SS H-SOK009SS H-SOK010SS H-SOK014SS PC002000 PC012200	GMDN:61664		

Product Family	Product Tradename	Item Number	Product Code(s)	Basic UDI-DI	Common Specifications
		PC012300 PC013100 PC013200 SOK001SS SOK002SS SOK003SS SOK004SS SOK005SS SOK006SS SOK007SS SOK008SS SOK009SS SOK010SS SOK011SS SOK012SS SOK013SS SOK016SS SOK200X350 SOK3030 SOK3045 SOK305X545 SOK3060 SOK350X350 SOK350X640 SOK375X300 SOK550X380 SOK560X1000 SOK560X1230 SOK560X1300 SOK560X1400 SOK560X280 SOK590X1200 SOK640X640			
Olej pro údržbu nástrojů  Účel použití: lubrikační prostředek pro údržbu zdravotnických prostředků	Lubrinol	02004	GMDN: 15772	084977100000000000000012M8	
Chirol Ultra  Účel použití: řešení pro očistu nástrojů  Odstranění nečistot z povrchu kovových nástrojů	Chirol Ultra	02110	GMDN: 63385	084977100000000000000013MA	

Jmenujeme tímto

Medical Device Safety Service (MDSS)  
Schiffgraben 41  
D-30175 Hannover  
Germany

autorizovaným evropským zástupcem podle Článku 2, odstavce 32 MDR

**Posouzení shodly dle:** příloha IV

**Vystaveno kým:**



**Podpis:**

**Datum:** 12/28/2020

**Jméno:** Kasey Koenig

**Funkce:** Director, Global Quality, Regulatory and DPO

**Vystaveno:** Key Surgical LLC  
8101 Wallace Rd.  
Eden Prairie, MN 55344  
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