



Declaration of Conformity

We, the manufacturer,
Wir, der Hersteller

Key Surgical GmbH
Zum Windpark 1
23738 Lensahn, Deutschland

ensure and declare with sole responsibility, that the following Class I non-sterile, non-measuring medical devices meet the provisions of the Council Directive 93/42/EEC (MDD) Annex IX for Medical Devices as amended by 2007/47/EC, which apply to them.

versichern und erklären in alleiniger Verantwortung, dass die nachfolgend unsterilen, nicht messenden Medizinprodukte der Klasse I mit den in Anhang IX der Richtlinie 93/42/EWG (MDD) für Medizinprodukte in der durch 2007/47/EG geänderten Fassung gelten.

Product Name Produktname	UMDNS Description UMDNS Beschreibung	Item number Artikelnummer	UMDNS Code	Rule (Per MDD) Regel (nach MDD)
Bite Blocks, non sterile Beißring, unsteril	Bite block Beißring	26002, 26003, 26004	10-405	1
Chirol Ultra	-	02110	-	1
Container filter with indicator Containerfilter mit Indikator	Filter, Steam Filter, Dampf	01140, 01143, 01145, 01148, 01152, 01153, 01158, 01188, 01189, 01312, 01314, 01315, 01317, 01321, 01322, 01323, 01327, 01330, 01346, 01347, 01348, 01355, 01356, 01363, 01365, 01367, 01368, 01369, 04111, 55-291-01-04, 61140, 71140, 91140	15-035	1
Container filter without indicator Containerfilter ohne Indikator	Filter, Steam Filter, Dampf	01141, 01142, 01144, 01149, 01157, 01167, 01168, 01181, 01183, 01186, 01194, 01196, 01198, 01300, 01304, 01306, 01318, 01319, 01331, 01332, 01350, 01366, 01373, 71141, 71194, 1070020, 26510, 27320, 27330, 27340, 27350, 27360	15-035	1
Enginol / Schlittenbahnöl	-	02005, 02006	-	1
Cart and Tray Liner Schaumstoffeinlagen	-	26108, 26109, 26110, 26111, 26112, 26113	16-222	1
Tip protectors made of foam Instrumentenschutztaschen aus Schaumstoff	-	26150, 26091, 26092, 26093, 26094, 26095	-	1
Hot air film – Sterilization packaging Heißluftfolie - Sterilisationsverpackung	Sterile packaging system Sterilisationsverpackung	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	13-735	1
Tip guards Instrumentenschutzkappen	-	01050, 01051, 01052, 01053, 01054, 01055, 01056, 01057, 01058, 01059, 01460, 01461, 01462, 01463, 01464, 01465, 01466, 01467, 01468, 01472, 01473, 01474, 01475, 01480, 01481, 01482, 01483, 01484, 01485, 01486, 01487, 01488, 01489, 01494, 01800, 01801, 01802, 01803, 01804, 01805, 01806, 01807, 01808, 01809, 01810, 01811, 01812, 01813, 01814, 01815, 01816, 01817, 01818, 01819, 01820,	16-222	1

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Product Name Produktname	UMDNS Description UMDNS Beschreibung	Item number Artikelnummer	UMDNS Code	Rule (Per MDD) Regel (nach MDD)
Tip guards Instrumentenschutzkappen	-	01821, 01822, 01823, 01824, 01825, 01826, 01827, 01828, 01829, 01830, 01831, 01832, 01833, 01834, 01835, 01836, 01837, 01838, 01839, 01840, 01841, 01842, 01843, 01844, 01845, 01846, 01847, 01848, 01850, 01851, 01852, 01853, 01854, 01855, 01856, 01857, 01858, 01859, 01860, 01861, 01862, 01863, 01865, 01866, 01867, 01868, 01869, 01870, 01871, 01872, 01873, 01874, 01875, 01876, 01877, 01878, 01879, 01880, 01881, 01884, 01885, 01886, 01887, 01888, 01889, 01890, 01891, 01892, 01893, 30000, 30001, 30002, 30003, 30003, 30004, 30005, 30016, 30017, 30006, 30007, 30008, 30009, 30010, 30011, 30012, 30013, 30014, 30015, 30016, 30017	16-222	1
Tip protectors Instrumentenschutztaschen	-	01469, 01470, 01471, 01476, 01477, 01478, 01479, 01492, 01496, 01499	16-222	1
Lubrinol	-	02004	-	1
Container	Sterilization container Sterilisationscontainer	28060, 28061, 28062, 28063, 28064, 28066, 28067, 28068, 28069, 28070, 28071, 28072, 28073, 28074, 28075, 28076, 28077, 28078, 28079, 28080, 28081, 28106, 28107, 28108, 28109, 28110, 28111, 28112, 28113, 28114, 28115, 28166, 28167, 28213, 28228, 28311, 28351, 28421	13-730	1
Cleaning brushes Reinigungsbürsten	Brushes Bürsten	09049, 09050, 09051, 09052, 09053, 09054, 09055, 09056, 09058, 09059, 09064, 09066, 09068, 09083, 09084, 09095, 09096, 09098, 09303, 09306, 09307, 09308, 09309, 09310, 09311, 09312, 09313, 09314, 09315, 09316, 09317, 09318, 09319, 09320, 09322, 09324, 09331, 09332, 09333, 09334, 09335, 09336, 09338, 09339, 09340, 09341, 09342, 09343, 09344, 09345, 09346, 09349, 09365, 09366, 09380, 09388, 09458, 09459, 09460, 09478, 09458, 09490, 09491, 09492, 09499, 09745, 09746, 09747, 26098, 26099, 26322, 26323, 26324, 26325, 26326, 26327, 26328, 26329, 26334, 26335, 26336, 26337, 26342, 26441, 26480, 26485, 26491, 26492, 26475, 26476, 26477, 26478, 45906, 45908, 45910, 45912, 45914, 96280.2, 96280.3, 26280.4, 96280.6, 96280.8, 96280.9, 96281.4, 96281.7	10-500	1
	Brush, endoscope cleaning Bürste, Endoskopreinigung	26022, 26020, 26021, 26482, 26025, 26028, 26481, 26027, 26090, 26305, 26026, 09356, 09353, 09352	17-143	1
Tape-Ex	-	02111	-	1
Textile Filter	Filter, Steam Filter, Dampf	01070, 01088, 01097, 01108, 01109, 01112, 01113, 01171, 01173, 01174, 01175, 01179, 01600, 01601, 01610, 01656, 01654, 01659, 01661, 01677, 01667, 01669, 01682, 01683, 01692,	15-035	1

Product Name Produktname	UMDNS Description UMDNS Beschreibung	Item number Artikelnummer	UMDNS Code	Rule (Per MDD) Regel (nach MDD)
Textile Filter	Filter, Steam Filter, Dampf	01691, 01694, 02305, 02306, 02314, 01067, 01606, 01616, 01617, 01618, 01619, 01620, 01629, 01631, 01636, 01642, 01665, 02315, 01060, 01061, 01062, 01063, 01064, 01065, 01066, 01071, 01072, 01073, 01074, 01075, 01076, 01077, 01078, 01079, 01080, 01081, 01082, 01083, 01084, 01085, 01086, 01087, 01089, 01090, 01091, 01092, 01093, 01094, 01095, 01096, 01098, 01099, 01100, 01101, 01102, 01103, 01104, 01105, 01106, 01107, 01111, 01114, 01115, 01170, 01172, 01176, 01177, 01178, 01602, 01603, 01604, 01605, 01607, 01608, 01609, 01611, 01612, 01655, 01068, 01653, 01651, 01652, 01657, 01658, 01660, 01177, 01662, 01664, 01106, 01099, 01083, 01078, 01666, 01676, 01674, 01673, 01672, 01668, 01671, 01675, 01684, 01685, 01686, 01687, 01688, 01690, 01693, 01695, 02300, 01696, 02303, 02302, 02307, 01096, 01678, 01663, 01063, 01681, 01680, 02301, 02304, 01670, 02312, 02313, 02311, 02309, 02310, 02308, 01069, 01613, 01614, 01615, 01621, 01622, 01623, 01624, 01625, 01626, 01627, 01628, 01630, 01632, 01633, 01634, 01635, 01637, 01638, 01639, 01640, 01641, 01643, 01644, 01645, 01646, 01647, 01648, 01649, 01650, 01679, 01689, 02316, 02317, 02318, 71170	15-035	1

Issued By / Ausgestellt von:

Signature/ Unterschrift:



Date: 23.07.2020

Name:

Tanja Dreesch

Position:

Quality Manager





Atitikties deklaracija

Mes, gamintojai

Key Surgical GmbH
Zum Windpark 1
23738 Lensahn, Vokietija

Atsakingai užtikrinam ir deklaruojame, kad žemiau išvardintos 1 klasės nesterilios, nepriskirtinos matavimo priemonės medicinos priemonės atitinka Direktyvos 93/42/EEC (MDD) dėl medicinos priemonių su pakeitimais, padarytais 2007/47 /EB, kurie joms taikomi IX priedo reikavimus.

Produkto pavadinimas	UMDNS paaiškinimas	Artiklio numeros	UMDN S kodas	MDD klasė
Bite Blocks, non sterile Beišring, unsteril Nesterilūs blokai	Bite block Nesterilus blokas	26002, 26003, 26004	10-405	1
Chirol Ultra	-	02110	-	1
Container filter with indicator Containerfilter mit Indikator Konteinerio filtras be indikatorių	Filter, Steam Filtrai, garai	01140, 01143, 01145, 01148, 01152, 01153, 01158, 01188, 01189, 01312, 01314, 01315, 01317, 01321, 01322, 01323, 01327, 01330, 01346, 01347, 01348, 01355, 01356, 01363, 01365, 01367, 01368, 01369, 04111, 55-291-01-04, 61140, 71140, 91140	15-035	1
Container filter without indicator Containerfilter ohne Indikator Konteinerio filtras be indikatorių	Filter, Steam Filtrai, garai	01141, 01142, 01144, 01149, 01157, 01167, 01168, 01181, 01183, 01186, 01194, 01196, 01198, 01300, 01304, 01306, 01318, 01319, 01331, 01332, 01350, 01366, 01373, 71141, 71194, 1070020, 26510, 27320, 27330, 27340, 27350, 27360	15-035	1
Enginol / Schlittenbahnöl	-	02005, 02006	-	1
Cart and Tray Liner Schaumstoffeinlagen Krepšelis ir dėko apsaugos	-	26108, 26109, 26110, 26111, 26112, 26113	16-222	1
Tip protectors made of foam Instrumentenschutztaschen aus Schaumstoff Apsaugos iš putų	-	26150, 26091, 26092, 26093, 26094, 26095	-	1
Hot air film - Sterilization packaging Heißluftfolie - Sterilisationsverpackung Karšto oro juosta - sterilizacijos pakuotė	Sterile packaging system Sterilumo užtikrinimo sistema	36201, 36202, 36203, 36204, 36205, 36206, 36207, 36208, 36209, 36210, 36211	13-735	1
Tip guards Instrumentenschutzkappen Apsaugos	-	01050, 01051, 01052, 01053, 01054, 01055, 01056, 01057, 01058, 01059, 01460, 01461, 01462, 01463, 01464, 01465, 01466, 01467, 01468, 01472, 01473, 01474, 01475, 01480, 01481, 01482, 01483, 01484, 01485, 01486, 01487, 01488, 01489, 01494, 01800,	16-222	1

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Produkto pavadinimas	UMDNS paaiškinimas	Artiklio numeras	UMDN S kodas	MDD klasė
		01801, 01802, 01803, 01804, 01805, 01806, 01807, 01808, 01809, 01810, 01811, 01812, 01813, 01814, 01815, 01816, 01817, 01818, 01819, 01820, 01821, 01822, 01823, 01824, 01825, 01826, 01827, 01828, 01829, 01830, 01831, 01832, 01833, 01834, 01835, 01836, 01837, 01838, 01839, 01840, 01841, 01842, 01843, 01844, 01845, 01846, 01847, 01848, 01850, 01851, 01852, 01853, 01854, 01855, 01856, 01857, 01858, 01859, 01860, 01861, 01862, 01863, 01865, 01866, 01867, 01868, 01869, 01870, 01871, 01872, 01873, 01874, 01875, 01876, 01877, 01878, 01879, 01880, 01881, 01884, 01885, 01886, 01887, 01888, 01889, 01890, 01891, 01892, 01893, 30000, 30001, 30002, 30003, 30003, 30004, 30005, 30016, 30017, 30006, 30007, 30008, 30009, 30010, 30011, 30012, 30013, 30014, 30015, 30016, 30017		
Tip protectors Instrumentenschutztaschen Apsaugos	-	01469, 01470, 01471, 01476, 01477, 01478, 01479, 01492, 01496, 01499	16-222	1
Lubrinol	-	02004	-	1
Container Konteineriai	Sterilization container Konteineriai sterilizacijai	28060, 28061, 28062, 28063, 28064, 28066, 28067, 28068, 28069, 28070, 28071, 28072, 28073, 28074, 28075, 28076, 28077, 28078, 28079, 28080, 28081, 28106, 28107, 28108, 28109, 28110, 28111, 28112, 28113, 28114, 28115, 28166, 28167, 28213, 28228, 28311, 28351, 28421	13-730	1
Cleaning brushes Reinigungsbürsten Šepetėliai instrumentams	Brushes Šepetėliai	09049, 09050, 09051, 09052, 09053, 09054, 09055, 09056, 09058, 09059, 09064, 09066, 09068, 09083, 09084, 09095, 09096, 09098, 09303, 09306, 09307, 09308, 09309, 09310, 09311, 09312, 09313, 09314, 09315, 09316, 09317, 09318, 09319, 09320, 09322, 09324, 09331, 09332, 09333, 09334, 09335, 09336, 09338, 09339, 09340, 09341, 09342, 09343, 09344, 09345, 09346, 09349, 09365, 09366, 09380, 09388, 09458, 09459, 09460, 09478, 09458, 09490, 09491, 09492, 09499, 09745, 09746, 09747, 26098, 26099, 26322, 26323, 26324, 26325, 26326, 26327, 26328, 26329, 26334, 26335, 26336, 26337, 26342, 26441, 26480, 26485, 26491, 26492, 26475, 26476, 26477, 26478, 45906, 45908, 45910, 45912, 45914, 96280.2, 96280.3, 26280.4, 96280.6, 96280.8, 96280.9, 96281.4, 96281.7	10-500	1
	Brush, endoscope cleaning Šepetelis endoskopų valymui	26022, 26020, 26021, 26482, 26025, 26028, 26481, 26027, 26090, 26305, 26026, 09356, 09353, 09352	17-143	1
Tape-Ex	-	02111	-	1
Textile Filter-Tekstiliniai filtrai	Filter, Steam	01070, 01088, 01097, 01108, 01109,	15-035	1

Produkto pavadinimas	UMDNS paaiškinimas	Artikelio numeras	UMDN S kodas	MDD klasė
	Filtrai, garai	01112, 01113, 01171, 01173, 01174, 01175, 01179, 01600, 01601, 01610, 01656, 01654, 01659, 01661, 01677, 01667, 01669, 01682, 01683, 01692, 01691, 01694, 02305, 02306, 02314, 01067, 01606, 01616, 01617, 01618, 01619, 01620, 01629, 01631, 01636, 01642, 01665, 02315, 01060, 01061, 01062, 01063, 01064, 01065, 01066, 01071, 01072, 01073, 01074, 01075, 01076, 01077, 01078, 01079, 01080, 01081, 01082, 01083, 01084, 01085, 01086, 01087, 01089, 01090, 01091, 01092, 01093, 01094, 01095, 01096, 01098, 01099, 01100, 01101, 01102, 01103, 01104, 01105, 01106, 01107, 01111, 01114, 01115, 01170, 01172, 01176, 01177, 01178, 01602, 01603, 01604, 01605, 01607, 01608, 01609, 01611, 01612, 01655, 01068, 01653, 01651, 01652, 01657, 01658, 01660, 01177, 01662, 01664, 01106, 01099, 01083, 01078, 01666, 01676, 01674, 01673, 01672, 01668, 01671, 01675, 01684, 01685, 01686, 01687, 01688, 01690, 01693, 01695, 02300, 01696, 02303, 02302, 02307, 01096, 01678, 01663, 01063, 01681, 01680, 02301, 02304, 01670, 02312, 02313, 02311, 02309, 02310, 02308, 01069, 01613, 01614, 01615, 01621, 01622, 01623, 01624, 01625, 01626, 01627, 01628, 01630, 01632, 01633, 01634, 01635, 01637, 01638, 01639, 01640, 01641, 01643, 01644, 01645, 01646, 01647, 01648, 01649, 01650, 01679, 01689, 02316, 02317, 02318, 71170		

Patvirtinta:

Parašas:

Vardas:

Pareigos:



Data: 23.07.2020

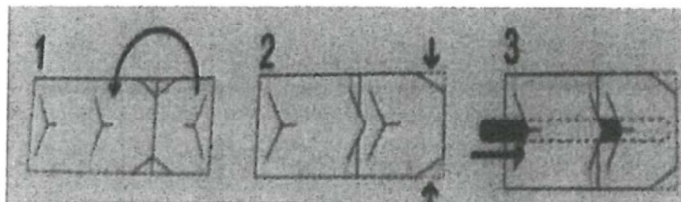
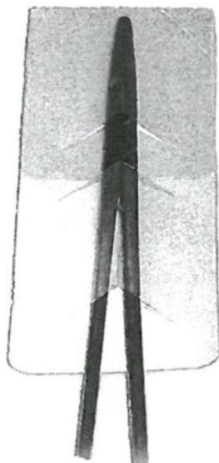
Tanja Dreesch

Kokybės vadovas

Plastikinės instrumentų aštrių dalių apsaugos (dydžiai pagal katalogą)

Paskirtis: skirtos profesionaliam naudojimui sveikatos priežiūros įstaigose, medicinos instrumentų aštrioms dalims uždengti prieš sterilizacijos procesą pakuojuant į neatsparias dūriams pakavimo medžiagas.

Naudojimas: parinkti apsaugą atitinkančią instrumento dydį. Sulankstyti apsaugą vadovaujantis paveikslėliais (pav. 1,2). Užmauti apsaugą ant instrumento aštrios dalies (kaip parodyta pav.3). Dabar instrumentą galima pakuoti tolimesnei sterilizacijai.



Priežiūra: prieš naudojimą suterštas apsaugas rekomenduojama plauti ir dezinfekuoti pagal įstaigoje numatytą tvarką. Apsaugos skirtos sterilizuoti garuose, esant 134°C temperatūrai.

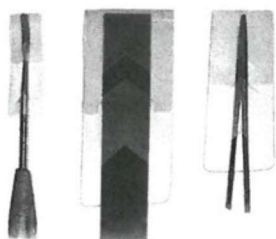
Šalinimas: Netinkamos naudoti apsaugos šalinamos kaip nepavojingos medicininės atliekos.

Klasifikavimas: instrumentų aštrių dalių apsaugos klasifikuojami kaip I klasės medicinos prietaisai pagal MDD 93/42/EEC.



Gamintojas/Tiekėjas: Key Surgical GmbH, Zum Windpark 1, 23738 Lensahn, Vokietija

Platintojas: L.R. Tamulio firma "Meditalika", Radvilų dvaro g.4, LT-48320 Kaunas, Lietuva
tel.: +370 37 22 22 23 e-paštas: info@meditalika.lt www.meditalika.lt



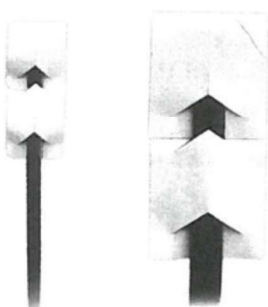
01477
01471
01476

How to use: First, the shorter flap is folded to the back and then pushed beneath the V-shaped opening. For narrow instruments the folding borders on each side can be folded inwards to prevent the instruments from slipping out. Lastly, the instruments are pushed through the punched openings, as shown in Figure 3.

heat resistant: up to 134 °C

maximum instrument width	working length	
up to 50 mm	140 mm	100 pieces
up to 25 mm	105 mm	1000 pieces
up to 10 mm	60 mm	1000 pieces

Single use tip protectors, made of carton

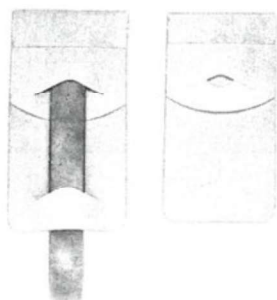


01492
01469
01470

heat resistant: up to 134 °C

maximum instrument width	working length	
up to 50 mm	140 mm	100 pieces
up to 25 mm	105 mm	1000 pieces
up to 10 mm	60 mm	1000 pieces

Single use tip protectors, made of carton



01499
01496

The tip protector is already folded and glued. Suitable for: slender hooks, slitting knives, sickle knives and septum knives.

heat resistant: up to 134 °C

maximum instrument width	working length	
up to 20 mm	105 mm	100 pieces
up to 20 mm	105 mm	1000 pieces

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