

Produkto pavadinimas	UMDNS paaiškinimas	Artikelio numeros	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:



Data: 23.07.2020

Vardas:

Tanja Dreesch

Pareigos:

Kokybės vadovas

LUBRINOL

lubrikantas medicinos prietaisams

Dėmesio

ši naudojimo instrukcija skirta profesionaliems naudotojams. Profesionalūs naudotojai privalo taikyti etiketėje ir saugos duomenų lape nurodytas darbų saugos ir sveikatos bei atliekų tvarkymo priemonės.

Savybės

Lubrikantas LUBRINOL yra pagamintas sintetinės alyvos pagrindu.

Skirtas nuplautiems medicinos prietaisams (jų jungtims, funkcinėms dalims) sutepti prieš naudojimą arba sterilizacijos procesus.

Priemonė pasižymi optimaliomis lubrikanto savybėmis, tolygiai pasiskirsto ant paviršiaus. Lubrinol yra fiziologiškai saugi priemonė.

Naudojimas

Lubrinol paskirstomas ant medicinos prietaisų paviršiaus purškiant. Prieš purškiant Lubrinol indelį būtina supurtyti.

Lubrinol purškiamas ant medicinos prietaisų paviršiaus per saugų 20-30 cm atstumą.

Lubrinol purškiamas tik ant išvalytų medicinos prietaisų paviršių.

Saugos ir rizikos frazės

nurodytos ant pakuotės

Laikymas

Lubrinol rekomenduojama laikyti kambario temperatūroje ir tik gamintojo pakuotėje.

Pakuotė

400 ml talpos indeliai

Klasifikavimas: klasifikuojamas kaip I klasės medicinos priemonė 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

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1 Product identifier
 - Trade name: 02004 Instrumentenpflege Lubrinal -400 ml-
 - Article number: P7000029, 75 0708
- 1.2 Relevant identified uses of the substance or mixture and uses advised against
 - No further relevant information available.
- Application of the substance / the mixture:
 - Lubricating oil
 - Maintenance product
- 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:
 - Key Surgical GmbH
 - Zum Windpark 1
 - 23738 Leisahn
 - Tel.: +49-4363-90590.0
 - Fax: +49-4363-90590.590
 - Email: info@keysurgical.de
 - Website: www.keysurgical.de
 - Further information obtainable from: Product safety department
 - 1.4 Emergency telephone number: During normal opening times: +49 4363 905900

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
 - Classification according to Regulation (EC) No 1272/2008
-  GHS02, flame
 - Aerosol 1 H222-H229 Extremely flammable aerosol, Pressurised container: May burst if heated.
 - Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.
 - Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- 2.2 Label elements
 - Labelling according to Regulation (EC) No 1272/2008
 - The product is classified and labelled according to the CLP regulation.
 - Hazard pictograms



- Signal word Danger
- Hazard-determining components of labelling:
 - Mineral oil
 - pentane
- Hazard statements
 - H222-H229 Extremely flammable aerosol, Pressurised container: May burst if heated.
 - H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
 - P102 Keep out of reach of children.
 - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Trade name: 02004 Instrumentenpflege Lubrinal -400 ml-

- P211 Do not spray on an open flame or other ignition source.
- P231 Do not pierce or burn, even after use.
- P273 Avoid release to the environment.
- P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
- P501 Dispose of contents container in accordance with local regional national international regulations.

- Additional information:
 - Buildup of explosive mixtures possible without sufficient ventilation.
- 2.3 Other hazards
- Results of PBT and vPvB assessment
 - PBT: Not applicable.
 - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 8042-47-5	Mineral oil	30-50%
EINECS: 232-453-8	Asp. Tox. 1, H304	
Reg.nr.: 01-2119487078-27		
CAS: 106-97-8	butane, pure	30-50%
EINECS: 203-448-7	Flam. Gas 1, H220	
Index number: 601-004-00-0		
Reg.nr.: 01-2119474691-32-XXXX		
CAS: 109-66-0	pentane	10-20%
EINECS: 203-692-4	Flam. Liq. 1, H224; Asp. Tox. 1, H304; Aquatic Chronic 2, H411; STOT SE 3, H336	
Index number: 601-006-00-1		
Reg.nr.: 01-2119459286-30		
CAS: 74-98-6	propane	10-20%
EINECS: 200-827-9	Flam. Gas 1, H220	
Index number: 601-003-00-5		
Reg.nr.: 01-2119486944-21-XXXX		
CAS: 75-28-5	isobutane	1-10%
EINECS: 200-857-2	Flam. Gas 1, H220; Press. Gas (Comp.), H280	
Index number: 601-004-00-0		
Reg.nr.: 01-2119485393-27-XXXX		

- Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
 - After skin contact: Generally the product does not irritate the skin.
 - After eye contact: Rinse opened eye for several minutes under running water.
 - After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed
 - No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed
 - No further relevant information available.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
 - Suitable extinguishing agents:
 - CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment: No special measures required.
- Additional information
- Collect contaminated fire fighting water separately. It must not enter the sewage system.

(Contd. of page 2)

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
- Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions:
- Do not allow product to reach sewage system or any water course.
- Inform respective authorities in case of seepage into water course or sewage system.
- Do not allow to enter sewers, surface or ground water.
- 6.3 Methods and material for containment and cleaning up:
- Dispose contaminated material as waste according to item 13.
- Ensure adequate ventilation.
- 6.4 Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling No special precautions are necessary if used correctly.
- Information about fire - and explosion protection:
- Do not spray onto a naked flame or any incandescent material.
- Keep ignition sources away - Do not smoke.
- Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C, i.e. electric lights. Do not pierce or burn, even after use.
- 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles:
- Observe official regulations on storing packagings with pressurised containers.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C, i.e. electric lights. Do not pierce or burn, even after use.
- Storage class: 2 B
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data, see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

109-66-0 pentane

IOELV Long-term value: 3000 mg m³, 1000 ppm

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment:
General protective and hygienic measures:
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

Trade name: 02004 Instrumentenpflege Lubrinal -400 ml-

- Wash hands before breaks and at the end of work.
- Respiratory protection: Not necessary if room is well-ventilated.
- Protection of hands:
- The glove material has to be impermeable and resistant to the product the substance the preparation.
- Due to missing tests no recommendation to the glove material can be given for the product the preparation the chemical mixture.
- Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- Material of gloves
- Nitrile rubber, NBR
- The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- Penetration time of glove material
- The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection: Not required.

(Contd. of page 3)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information	
Appearance:	aerosol
Form:	Colourless
Colour:	Characteristic
Odour:	Not determined
Odour threshold:	
pH-value:	Not determined
Change in condition	
Melting point/freezing point:	Undetermined
Initial boiling point and boiling range:	Not applicable, as aerosol.
Flash point:	-60 °C
Flammability (solid, gas):	Not applicable.
Ignition temperature:	285 °C
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation of explosive air vapour mixtures are possible.
Explosion limits:	
Lower:	1.4 Vol %
Upper:	10.9 Vol %
Vapour pressure at 20 °C:	2,600 hPa
Density at 20 °C:	0,64 g cm ³
Relative density	Not determined
Vapour density	Not determined.
Evaporation rate	Not applicable.
Solubility in / Miscibility with water:	Not miscible or difficult to mix.
Partition coefficient: n-octanol/water:	Not determined.

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- Viscosity: Not determined.
- Dynamic Kinematics: Not determined.
- Solvent content: 67.5 %
- Organic solvents: 67.50 %
- VOC (EC): No further relevant information available.
- 9.2 Other information

(Contd. of page 4)

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity based on available data, the classification criteria are not met.

LD₅₀/LC₅₀ values relevant for classification:

8042-47-5 Mineral oil	
Oral LD ₅₀	> 2.000 mg/kg (rat)
Dermal LD ₅₀	> 2.000 mg/kg (rabbit)
109-66-0 pentane	
Oral LD ₅₀	> 5.000 mg/kg (rat)
Inhalative LC ₅₀ 4 h	> 20 mg/l (rat)

- Primary irritant effect: Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
 - Germ cell mutagenicity Based on available data, the classification criteria are not met.
 - Carcinogenicity Based on available data, the classification criteria are not met.
 - Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard
 - May be fatal if swallowed and enters airways.

(Contd. on page 6)

SECTION 12: Ecological information

- 12.1 Toxicity
 - Aquatic toxicity: No further relevant information available.
 - 12.2 Persistence and degradability No further relevant information available.
 - 12.3 Bioaccumulative potential No further relevant information available.
 - 12.4 Mobility in soil No further relevant information available.
- Ecotoxicological effects:
 - Remark: Harmful to fish

Trade name: 02004 Instrumentenpflege Lubrinol -400 ml-

- Additional ecological information:
- General notes: Harmful to aquatic organisms
- Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
- Do not allow product to reach ground water, water course or sewage system.
- Danger to drinking water if even small quantities leak into the ground.
- 12.5 Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

(Contd. of page 5)

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
- Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- European waste catalogue
- 15 01 10* packaging containing residues of or contaminated by hazardous substances
- 15 01 04 metallic packaging
- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number: UN1950
- ADR, IMDG, IATA: 1950 AEROSOLS
AEROSOLS
AEROSOLS, flammable
- 14.2 UN proper shipping name: ADR
IMDG
IATA
- 14.3 Transport hazard class(es): ADR

Class Label: 2.5F Gases, 2.1
IMDG, IATA



- Class Label: 2.1
2.1

- 14.4 Packing group: Void
- ADR, IMDG, IATA

- 14.5 Environmental hazards: No
- Marine pollutants: Warning: Gases.
- 14.6 Special precautions for user

(Contd. on page 7)

Trade name: 02004 Instrumentenpflege Lubrirol -400 ml-

(Contd. of page 6)	
Hazard identification number (Kemler code):	I-D,S-U
EMIS Number:	SW1 Protected from sources of heat.
Storage Code	SW22 For AEROSOLS with a maximum capacity of 1 litre; Category A. For AEROSOLS with a capacity above 1 litre; Category B. For WASTE AEROSOLS: Category C, Clear of living quarters. SG69 For AEROSOLS with a maximum capacity of 1 litre; Segregation as for class 9, Slow "separated from" class 1 except for division 1.4. For AEROSOLS with a capacity above 1 litre: Segregation as for the appropriate subdivision of class 2. For WASTE AEROSOLS: Segregation as for the appropriate subdivision of class 2.
Segregation Code	
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
· Limited quantities (LQ)	II, Code: E0
· Excepted quantities (EQ)	Not permitted as Excepted Quantity
Transport category	2
Tunnel restriction code	D
IMDG	
· Limited quantities (LQ)	II, Code: E0
· Excepted quantities (EQ)	Not permitted as Excepted Quantity
UN "Model Regulation":	UN 1950 AEROSOLS, 2.1

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I Note of the ingredients is listed.
- Seveso category P3a FLAMMABLE AEROSOLS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 150 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.
- Relevant phrases**
- H220 Extremely flammable gas.
- H224 Extremely flammable liquid and vapour.
- H280 Contains gas under pressure; may explode if heated.
- H304 May be fatal if swallowed and enters airways.
- H336 May cause drowsiness or dizziness.
- H411 Toxic to aquatic life with long lasting effects.
- Department issuing SDS:** Product safety department

(Contd. on page 8)

Trade name: 02004 Instrumentenpflege Lubrirol -400 ml-

(Contd. of page 7)	
Abbreviations and acronyms:	
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)	
IMDG: International Maritime Code for Dangerous Goods	
IATA: International Air Transport Association	
GHS: Globally Harmonized System of Classification and Labelling of Chemicals	
ELINCS: European Inventory of Existing Commercial Chemical Substances	
CAS: Chemical Abstracts Service database	
WDC: Volatile Organic Compounds (VOC)	
LC50: Lethal concentration 50 percent	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: Very Persistent and Very Bioaccumulative	
Flam. Gas 1: Flammable gases - Category 1	
Aerosol 1: Aerosols - Category 1	
Press. Gas (Comp): Gas under pressure - Compressed gas	
Flam. Liq. 1: Flammable liquids - Category 1	
STOPE 3: Specific target organ toxicity (single exposure) - Category 3	
Acq. Tox 1: Aquatic toxicity - Category 1	
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2	
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3	
* Data compared to the previous version altered.	

Žymėjimo plokštelės plovimo ir dezinfekcijos krepšiams

Plokštelės pagamintos iš plastiko, atsparaus plovimui ir dezinfekcijai automatinuose plautuvuose bei sterilizacijai (vandens garais, EO ir kt.). Plokštelės yra daugkartinio naudojimo, atlaiko aukštų temperatūrų 134°C (+4°C) poveikį.

Ant plokštelės žymekliu surašoma visa reikalinga informacija (pvz. skyriaus pavadinimas, instrumentų pavadinimas ir kt.)

Plokštelė prie plovimo-dezinfekavimo krepšio tvirtinama specialiomis tampriomis silikoninėmis tvirtinimo detalėmis/kniedėmis. Tvirtinimo detalės skirtos daugkartiniam naudojimui, jos atsparios plovimui ir dezinfekcijai automatinuose plautuvuose bei sterilizacijai vandens garais, esant 134°C (+4°C), EO ir kt.

Galima rinktis iš plačios spalvų gamos: balta, raudona, melsva, gelsva, žalsva, kt. Dėl spalvų papildomai teirautis pas pardavėją.

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

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tel.: +370 37 22 22 23 e-paštas: info@meditalika.lt www.meditalika.lt

PP-Mesh basket labels for marking mesh baskets, durable material, made of synthetic material, 90 x 33 mm

REF

pack. unit

heat resistant: up to 134 °C
 material: polypropylene (PP)
 laser labeling: technically not feasible
 P-touch fit: no



01423	red	100 pieces
01424	dark green	100 pieces
01996	light green	100 pieces
01425	dark blue	100 pieces
01997	light blue	100 pieces
01426	yellow	100 pieces
01427	black	100 pieces
01428	white	100 pieces
01429	brown	100 pieces
01430	orange	100 pieces
01431	natural colour	100 pieces

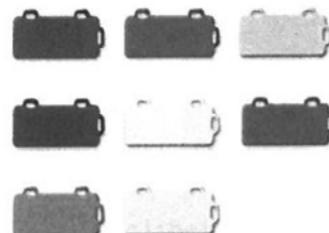


PP-Mesh basket labels for marking mesh baskets, durable material, made of synthetic material, 90 x 50 mm

heat resistant: up to 134 °C
 material: polypropylene (PP)
 laser labeling: technically not feasible
 P-touch fit: no
 durable material



01432	red	100 pieces
01433	dark green	100 pieces
01998	light green	100 pieces
01434	dark blue	100 pieces
01999	light blue	100 pieces
01435	yellow	100 pieces
01436	black	100 pieces
01437	white	100 pieces
01438	brown	100 pieces
01439	orange	100 pieces
01440	natural colour	100 pieces



PTL-Mesh basket labels for marking mesh baskets, durable material, made of synthetic material, 90 x 33 mm

heat resistant: up to 134 °C
 P-touch fit
 laser imprint with text and barcode possible,
 green labels can only be engraved with text

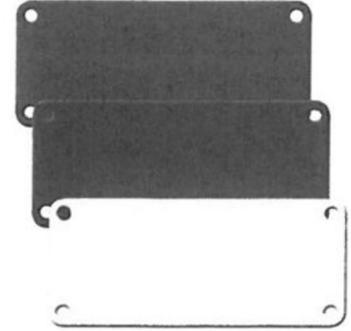


01900	red	100 pieces
01972	coral red	100 pieces
01901	green	100 pieces
01962	dark blue	100 pieces
01902	light blue	100 pieces
01903	yellow	100 pieces
01912	black	100 pieces
01904	white	100 pieces
01905	orange	100 pieces
01956	brown	100 pieces
01976	pink	100 pieces
01977	purple	100 pieces



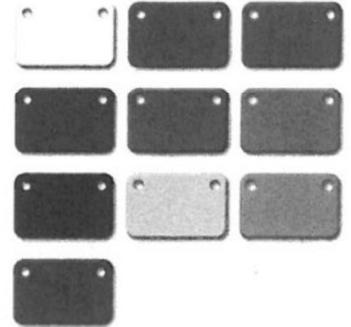
Tie-on PTL-tags, durable material, made of synthetic material, 90 x 40 mm

REF		pack. unit
	heat resistant: up to 134 °C laser labeling: with text and barcode possible P-touch fit	
02255	light red	100 pieces
02253	light blue	100 pieces
02254	white	100 pieces



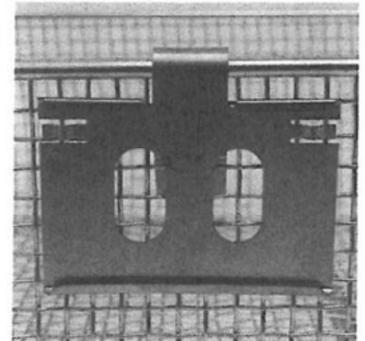
PTL-plastic labels for marking mesh baskets also suitable for Wagner containers, durable material, 60 x 40 mm

REF		pack. unit
	heat resistant: up to 134 °C suitable for: REF 01498, REF 04186 and REF 04189 P-touch fit laser imprint with text and barcode possible, green labels can only be engraved with text	
01948	white	100 pieces
01949	red	100 pieces
01950	green	100 pieces
01969	dark blue	100 pieces
01951	light blue	100 pieces
01952	orange	100 pieces
01953	black	100 pieces
01954	yellow	100 pieces
01990	pink	100 pieces
01991	purple	100 pieces



Mesh basket label holder, made of stainless steel, with clip durable material for PTL-plastic labels for marking mesh baskets, 60 x 40 mm

01498	heat resistant suitable for: REF 01948 - REF 01991	25 pieces
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37-

Vienkartinio naudojimo popieriniai filtrai konteineriams (dydžiai pagal katalogą)

Paskirtis:

filtras skirtas dėti į daugkartinio naudojimo sterilizacijos konteinerius.

Naudojimas:

filtras dedamas į konteineriujje filtrui numatytą vietą (pagal konteinerio gamintojo nurodymus).

Filtras yra naudojamas vienkartiniai.

Prieš pakartotiną konteinerio naudojimą, filtras turi būti išimtas iš konteinerio ir pakeistas nauju.

Pastaba:

priklausomai nuo rūšies filtrai gali būti su ir be proceso poveikio indikatorius ant jo.

Kai filtras yra su I tipo proceso cheminiu indikatoriumi (atitinkančiu EN 11140-1), pastarasis, įvykus sterilizacijos procesui, turi pakeisti spalvą (pagal taikomą sterilizacijos būdą). Nurodymai indikatorius spalvos pasikeitimui po sterilizacijos pateikti ant filtro, šalia cheminio indikatorius.

Laikymas:

prieš naudojimą filtras turi būti laikomas gamintojo pakuotėje, atokiau nuo cheminių medžiagų ir padidintos drėgmės.

Šalinimas:

po panaudojimo filtras priskiriamas nepavojingų medicininių atliekų grupei ir šalinamas pagal įstaigos patvirtintą tvarką.

Klasifikavimas: klasifikuojami kaip I klasės medicinos priemonė 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

Container paper filters for Aesculap containers according to ISO 11607-1 / for single use

REF pack. unit

white
 filter imprint: with functional information
 diameter: 190 mm
 round filter
 hole punching: central Ø 6 mm



01140	with steam indicator	500 pieces
01152	with steam indicator, packed at 100 pcs.	500 pieces
01141	without indicator	500 pieces

Container paper filters for Aesculap containers according to ISO 11607-1 / for single use

miniset filter

white
 rectangular filter
 size: 118 x 235 mm
 with pointed corners



01148	filter imprint: with functional information with steam indicator	200 pieces
01186	filter imprint: blank, without indicator	200 pieces

Container paper filters for Aesculap containers according to ISO 11607-1 / for single use

01317	white filter imprint: with functional information rectangular filter size: 170 x 230 mm with pointed corners with steam indicator	500 pieces
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Container paper filters for Aesculap containers according to ISO 11607-1 / for single use

white
 rectangular filter
 size: 230 x 230 mm

01153	filter imprint: with functional information with bevelled corners with steam indicator	500 pieces
01142	filter imprint: blank with bevelled corners without indicator	500 pieces
01149	filter imprint: blank with pointed corners without indicator	500 pieces



CHEMINIS PAKETO INDIKATORIUS C-V-P

Paskirtis

Lipus vidinis paketo cheminis indikatorius-etiketė naudojamas vandenilio peroksido plazmos sterilizatoriuose nustatyti, ar paketo viduje buvo pasiektos sterilizacijos sąlygos.

Tinka klijuoti į paciento ir sterilizacinės dokumentus, krovinio registracijos korteles.

Aprašymas: vienguba etiketė. Indikatoriaus-etiketės sudėtyje nėra celiuliozės. Indikatoriaus kurio šone yra violetinės spalvos cheminių indikatorinių dažų taškas, dešiniajame krašte – spalvos pasikeitimo etalonas rausvos spalvos taškas. Indikatorius skirtas H₂O₂ sterilizacijos kontrolei.

Naudojimas: indikatorius-etiketė įdedamas į kiekvieno sterilizuojamų gaminių paketo (paketų, konteinerių, maišelių) vidų, į sunkiausiai plazmai pasiekiamą vietą arba prie didžiausio sterilizuojamo paketo instrumento. Naudojamas nustatyti, ar paketo viduje buvo pasiektos būtinos sterilizacijos proceso sąlygos. Prieš sterilizuotų gaminių panaudojimą būtina įvertinti indikatoriaus spalvos pasikeitimą. Panaudojus sterilizuotus gaminius, indikatorius-etiketė klijuojama į krovinio registracijos korteles, kitus dokumentus.

Rezultatų vertinimas: Paketo viduje, pasiekus reikiamas sterilizacijos sąlygas, indikatoriaus-etiketės cheminių dažų spalva pakinta iš violetinės į rausvą. Jei spalva nepakinta, tai reiškia, kad sterilizacijos procesas neefektyvus. Tokiu atveju sterilizuotus gaminius būtina sterilizuoti pakartotinai.

Laikymas: sausoje tamsioje patalpoje, kambario temperatūroje. Gaminių galiojimo laikas pažymėtas ant pakuotės.

Pakuotė: pakuotėje yra 400, 800, 3200 vnt. indikatorių.

Šalinimas: panaudoti ir nepanaudoti indikatoriai-etiketės šalinami kaip buitinės atliekos.

Gamintojas: gke gmbh. Vokietija

Declaration of Conformity

gke Steri Record® Indicators to monitor sterilization processes

are available from *gke* as the following product variations according to EN ISO 11140-1:

Art. no.	Product code	Pack size	Sterilization process	Indicator type according EN ISO 11140-1		
BDS introduction packs						
211-110	C-S-BDS-EU-HPCD-KIT	1 + 100	Steam	Type 2		
211-150	C-S-BDS-EUH-RCPCD-KIT					
211-120	C-S-BDS-EU-RCPCD-KIT					
211-130	C-S-BDS-USA-RCPCD-KIT					
Indicator refill pack for all <i>gke</i> BDS-Tests						
211-111	C-S-BDS-SV1	100				
211-112		250				
211-115		500				
Batch monitoring introduction packs						
211-260	C-S-PM-HL-HPCD-KIT	1 + 100				
211-263	C-S-PM-HL-RCPCD-KIT					
211-264	C-S-PM-HL-OCPCD-KIT					
211-253	C-S-PM-SHL-RCPCD-KIT					
211-254	C-S-PM-SHL-OCPCD-KIT					
Indicator refill packs for all <i>gke</i> batch monitoring systems						
211-252	C-S-PM-SV1	250	EO LTSF H ₂ O ₂	n.a.		
211-255		500				
212-202	C-E-PM	250				
213-203	C-F-PM					
214-203	C-V-PM					
Package monitoring multi-variable indicators						
211-403	C-S-P-4-SV1	3200			Steam	Type 4
212-360	C-E-P-4-SV3				EO	
214-221	C-V-P ✓	400			H ₂ O ₂	n.a.
214-222		800				
214-223		3200				
Package monitoring integrating indicators						
211-224	C-S-P-5-SV1	400	Steam	Type 5		
211-225		800				
211-226		3200				
211-230	C-S-P-5-78x48-SA-SV1	1000				
211-235		500				
211-220	C-S-P-5-58x35-SV1	1000				
211-222		200				
212-206	C-E-P-5-58x35-W-SV3	200			EO	
213-206	C-F-P-5-58x35-W-SV4				LTSF	
214-206	C-V-P-58x35-W				H ₂ O ₂	
Package monitoring emulating indicators						
211-241	C-S-P-6-SV1	2000	Steam	Type 6		
211-242		500				
211-243		250				
211-238	C-S-P-6-SV2	2000				
211-239		500				
211-240		250				

Notice: On all *gke* packages, an additional letter code has been added to the 6-digit article number. The additional letter code refers to the language and/or customized version. It is only added on the outside label. The inside of the pack is identical to the article numbers in the above table. All articles with the same 6-digit number have the same specifications.

We hereby declare under our sole responsibility that above mentioned integrating indicators have been tested in the *gke* application laboratory and are in conformity with the European and ISO standard EN ISO 11140-1 for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. The corresponding indicator types are available in the above table. The indicators listed above are tested in a resistometer according EN ISO 18472.

According to ISO 11140-1, 5.9 the indicators do not release any particles or toxic substances in sufficient quantities to cause a health hazard. The colour of the indicators remains constant after the sterilization process has passed successfully and does not fade back to the colour before sterilization for at least 5 years under the condition the indicator is not stored in contact with oxidation agents like H₂O₂ or other chemicals.

The above mentioned products manufactured by *gke*-GmbH are produced in accordance with the requirements of the Medical Device Directive 93/42/EEC and the Medical Device Regulation 2002:618.

This document certifies that the above performance criteria and the *gke* requirements for quality control are met. The continuous quality is guaranteed by our quality management system according to EN ISO 13485*.



Waldems-Esch, 2016-04-08

Dipl.-Ing. Dr. Ulrich Kaiser
R & D-Manager

gke-GmbH
Auf der Lind 10
D-65529 Waldems-Esch, Germany

* This certificate is available on the *gke* homepage www.gke.eu.

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VERTIMAS Į LIETUVIŲ KALBĄ

ATITIKTIES DEKLARACIJA

gke-Steri-Record® indikatoriai, skirti kontroliuoti sterilizacijos procesus
gke tiekia tokia produktų variacijas pagal EN ISO 11140-1:

Art. Nr.	Produkto kodas	Pakuotės dydis	Sterilizacijos procesas	Indikatoriaus tipas pagal EN ISO 11140-1		
BDS startiniai paketai						
211-110	C-S-BDS-EU-HPCD-KIT	1+100	Garai	2 tipas		
211-150	C-S-BDS-EUH-RCPCD-KIT					
211-120	C-S-BDS-EU-RCHPCD-KIT					
211-130	C-S-BDS-USA-RCPCD-KIT					
Papildymo pakuotės gke BDS testams						
211-111	C-S-BDS-SV1	100				
211-112		250				
211-115		500				
Krovinio kontrolės startiniai paketai						
211-260	C-S-PM-HL-HPCD-KIT	1-100				
211-263	C-S-PM-HL-RCPCD-KIT					
211-264	C-S-PM-HL-OCPCD-KIT					
211-253	C-S-PM-SHL-RCPCD-KIT					
211-254	C-S-OM-SHL-OCPCD-KIT					
Papildymo pakuotės gke krovinio kontrolės sistemai						
211-252	C-S-PM-SV1	250				
211-255		500				
211-202	C-E-PM	250	EO			
213-203	C-F-PM		LTSF			
214-203	C-V-PM		H2O2	n.d.		
Multiparametriniai indikatoriai paketų kontrolei						
211-403	C-S-P-4-SV1	3200	Garai	4 tipas		
212-360	C-E-P-4-SV3		EO			
214-221	C-V-P	400	H2O2	n.d.		
214-222		800				
214-223		3200				
Integruojantys indikatoriai paketų kontrolei						
211-224	C-S-P-5-SV1	400	Garai	5 tipas		
211-225		800				
211-226		3200				
211-230	C-S-P-5-78x48-SA-SV1	1000				
211-235		500				
211-220	C-S-P-5-58x35-SV1	1000				
211-222		200				
212-206	C-E-P-5-58x35-W-SV3	200			EO	
213-206	C-F-P-5-58x35-W-SV4				LTSF	
214-206	C-V-P-58x35-W				H2O2	n.d.
Emuliuojantys indikatoriai paketų kontrolei						
211-241	C-S-P-6-SV1	2000	Garai	6 tipas		
211-242		500				
211-243		250				

211-238	C-S-P-6-SV2	2000	
211-239		500	
211-240		250	

Pastaba. Ant visų gke produktų pakuočių yra pridėtas papildomas raidinis kodas prie šešiaženklį prekės kodo. Papildoma raidė tai nuoroda į kalbą arba prekės modifikavimą. Raidė papildomai rašoma tik ant išorinės pakuotės, viduje skaitmeniniai kodai tokie patys kaip pateikti aukščiau. Visi gaminiai, turintys tuos pačius šešiaženklį numerius, turi tas pačias specifikacijas.

Šiuo mes atsakingai deklaruojame, kad aukščiau minėti integruojantys indikatoriai buvo testuoti *gke* laboratorijoje ir atitinka Europos ir ISO standartą EN-ISO 11140-1 garų, etileno oksido, formaldehido ir vandenilio peroksido sterilizacijos procesams. Cheminių indikatorių tipai pateikti lentelėje. Aukščiau išvardinti indikatoriai buvo testuoti rezistometre pagal EN ISO 18472.

Pagal ISO 11140-1, 5.9 indikatoriai nepalieka jokių dalelių ar toksinių substancijų pakankamos kiekybės, kad sukeltų pavojus sveikatai. Indikatorių spalva po sėkmingos sterilizacijos išlieka nekintanti ir lieka stabili ne mažiau kaip 5 metai, esant sąlygoms, kai indikatoriai nėra laikomi kontakte su oksiduojančiomis medžiagomis (tokiomis kaip H₂O₂ ar kitais chemikalais).

Visi aukščiau minėti produktai pagaminti gke-GmbH, pagal Medicinos Prietaisų Direktyvos 93/42/EEC ir Medicinos Prietaisų Taisyklių 2002:618 reikalavimus.

Aukščiau minėti produktai pagaminti gke-GmbH pagal Medicinos Prietaisų Direktyvos 93/42/EEC ir Medicinos Prietaisų Taisyklių 2002:618 reikalavimus.

Dokumentas liudija, kad aukščiau minėti įvykdymo kriterijai ir *gke* reikalavimai kokybės kontrolei yra patenkinti. Nuolatinė kontrolė užtikrina mūsų kokybės valdymo sistemą, parengta pagal EN-ISO 13485.

(parašas)

Waldems-Esch, 2016-04-08

Dipl. Inž. Dr. Ulrich Kaiser

gke-GmbH

Auf der Lind 10 D-65529 Waldems-Esch

Germany

751-019 EN V15

Rašalo kasetė rankiniam spausdintuvui 1 tipo indikatoriums

Rašalo kasetė skirta naudoti su rankiniu spausdintuvu 1 tipo indikatoriums. Kasetės rašalas yra atsparus vandens garų sterilizacijai, EO, FO dujų sterilizacijai, todėl po sterilizacijos ciklo išlieka gerai matomi simboliai ant indikatorių ir neišblanksta daugiau kaip 3 metus.

Naudojimas: atsargiai dviem pirštais išimkite rašalo kasetę iš plastikinės pakuotės ir stabiliai įstatykite į rankinį spausdintuvą.

Gamintojas: gke GmbH, Vokietija



Silikoniniai dirželiai (dydžiai pagal katalogą)

Dirželiai pagaminti iš tampraus silikono, atsparaus plovimui ir dezinfekcijai automatiniuose plautuvuose bei sterilizacijai aukštoje temperatūroje (vandens garai, kt.).

Dirželiai atlaiko aukštų temperatūrų 134°C poveikį.

Silikoniniai dirželiai skirti įvairių instrumentų markiravimui, žymėjimui, surišimui, komplektavimui.

Galima rinktis iš plačios spalvų gamos: balta, raudona, melsva, gelsva, kt.

Pastaba: dėl spalvų papildomai teirautis pas pardavėją.

Dirželiai turi patogius ir reguliuojamus darbinio ilgio fiksatorius.

Naudojimas: vieną žymeklio galą perkištį per kitame žymeklio gale esančią plokštelę ir užfiksuoti ant instrumento (-ų), krepšelio, medicinos prietaiso, laidų, kt.

Markiruoti instrumentai gali būti sudedami į plovimo-dezinfekcijos krepšius ir plaunami plovimo mašinose, jie gali būti valomi ir dezinfekuojami rankiniu būdu, sterilizuojami sočiaisiais vandens garais, EO ir kt.

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

Cable binder made of synthetic material

REF		pack. unit	
	to affix mesh basket labels heat resistant: up to 134 °C		
09461	red, size: 98 x 2.5 mm	100 pieces	
09462	green, size: 98 x 2.5 mm	100 pieces	
09463	blue, size: 98 x 2.5 mm	100 pieces	
09464	yellow, size: 98 x 2.5 mm	100 pieces	
09482	natural colour, size: 200 x 3.5 mm	100 pieces	

Cable binder made of silicone to bundle instruments

REF		pack. unit	
	heat resistant: up to 134 °C		
	length: 110 mm		
09231	natural colour	100 pieces	
09235	red	100 pieces	
09236	yellow	100 pieces	
09237	green	100 pieces	
09238	blue	100 pieces	
09369	violet	100 pieces	
09370	black	100 pieces	
	length: 210 mm		
09239	red	100 pieces	
09240	yellow	100 pieces	
09241	green	100 pieces	
09242	blue	100 pieces	
09371	violet	100 pieces	
09372	black	100 pieces	

Cable binder made of silicone to bundle instruments

REF		pack. unit		
	heat resistant: up to 134 °C			
	length: 60 mm (mini)			
09246	natural colour	100 pieces		
09252	green	100 pieces		
09253	blue	100 pieces		
09254	yellow	100 pieces		
09255	black	100 pieces		
09256	red	100 pieces		
09257	white	100 pieces		
09258	orange	100 pieces		
09259	brown	100 pieces		
09260	grey	100 pieces		
09261	violet	100 pieces		
09397	light blue	100 pieces		
	length: 110 mm (midi)			
09373	natural colour	100 pieces		
09374	red	100 pieces		
09375	yellow	100 pieces		
09376	green	100 pieces		
09377	blue	100 pieces		

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Dispenser for 1 reel adhesive tape

REF		pack. unit
09001	version: heavy duty design maximum reel width: 25 mm	1 piece

09005	Replacement knife for dispenser (REF 09001)	1 piece
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**Dispenser for 1 reel adhesive tape**

09035	strip length can be preset from 1 cm to 10 cm version: with tape dispenser maximum reel width: 25 mm	1 piece
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09036	Knife holder for dispenser (REF 09035)	1 piece
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09007	Replacement knife for dispenser (REF 09035)	1 piece
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**Dispenser for up to 2 reels adhesive tape**

09002	version: heavy duty desing For one 50 mm wide adhesive tape reel or two reels with 25 mm each	1 piece
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**Dispenser for up to 2 reels adhesive tape**

09003	can be rotated 360° version: with bolts and suction cup assembling for one 50 mm wide adhesive tape reel or two reels with 25 mm each	1 piece
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