

KONFORMITÄTSERKLÄRUNG
Declaration of Conformity

KFE 0802-10

Wir / We Lohmann & Rauscher International GmbH & CO. KG
Westerwaldstraße 4, 56579 Rengsdorf, GERMANY

Erklären in alleiniger Verantwortung, dass das Produkt (die Produktgruppe)
Declare on our own responsibility that the products (group of products)

Raucodrape® Programm bestehend aus / *Raucodrape® program consisting of*
Raucodrape®, Raucodrape® PRO, Raucodrape® SMART

(Bezeichnung/Name)

REF siehe Anlage / s. Annex

GMDN-Code siehe Anlage / s. Annex

Den einschlägigen Anforderungen der Richtlinie 93/42/EWG entspricht/
meets all the requirements of the Directive 93/42/EEC which apply to him

Sterile Varianten

Sterile variants

Konformitätsbewertungsverfahren/
Conformity Assessment procedure

Anhang V + Anhang VII
Annex V + Annex VII

Klassifizierung, Regel/
Classification, Rule

Is, 1, 5

Benannte Stelle (falls zutreffend)/
Notified Body (if applicable)

TÜV SÜD Product Service
 GmbH (CE0123)
 Ridlerstraße 65
 80339 München
 GERMANY


Datum der ersten CE-Kennzeichnung/
Date of the first CE-Labeling

2015-11-03

Zertifikat (gültig bis)/
Certificate (valid until)

G2S 045286 0075 (2024-05-26)

Neuwied, am 2021-06-17
 Ort, Datum /place, date



Oliver Opitz
 Leiter Qualitätsmanagement / Qualitätssicherung
 Director of Quality Management / Quality Assurance

REF	Product name	GMDN
Sterile Products		
15965	RD camera cover tel 13x250	45021
15966	RD camera cover rev 13x250	45021
33001	RD drape sheet 38x45/2-layer	47783
33002	RD drape sheet 45x75/2-layer	47783
33003	RD drape sheet 75x90/2-layer	47783
33004	RD PRO OR drape sheet 150x240/2-layer	47783
33005	RD PRO OR drape sheet 75x90/2-layer	47783
33006	RD OR drape sheet soft 90x110	47783
33008	RD PRO OR drape sheet 100x150/2-layer	47783
33009	RD PRO OR drape sheet 150x180/2-layer	47783
33010	RD PRO adhesive drape 50x50/2-layer	47783
33011	RD PRO adhesive drape 50x75/2-layer	47783
33012	RD PRO adhesive drape 75x75/2-layer	47783
33013	RD PRO adhesive drape 75x90/2-layer	47783
33015	RD PRO adhesive drape 150x180/2-layer Plus	47783
33016	RD PRO adhesive drape 175x180/2-layer	47783
33017	RD PRO adhesive drape 175x180/2-layer Plus	47783
33018	RD PRO adhesive drape 150x240/2-layer	47783
33019	RD PRO adhesive drape 150x250/2-layer Plus	47783
33020	RD PRO adhesive drape 90x110/2-layer	47783
33021	RD PRO adhesive drape 190x225/2-layer Plus	47783
33022	RD PRO adhesive drape 90x150/2-layer	47783
33023	RD PRO adhesive drape 175x300/3-layer	47783
33024	RD PRO adhesive drape 175x300/2-layer LRF Bulk	47783
33025	RD PRO adhesive drape 150x180/2-layer	47783
33038	RD PRO Vertical drape 250x330	47783

REF	Product name	GMDN
Sterile Products		
33039	RD PRO Gyn-Cyst-drape 175x90/2-layer	47783
33040	RD fenestrated drape 45x75/2-layer	47783
33041	RD PRO fenestrated drape 50x60/2-layer self-adhesive	47783
33042	RD fenestrated drape 75x90/2-layer	47783
33043	RD PRO fenestrated drape 75x90/2-layer self-adhesive	47783
33044	RD PRO fenestrated drape 120x150/2-layer self-adhesive	47783
33045	RD PRO maxillo facial drape 112,5x150/2-layer (wrapped)	47783
33046	RD PRO fenestrated drape 150x200/2-layer self-adhesive	47783
33047	RD Epidural drape sheet 60x75/2-layer self-adhesive	47783
33049	RD PRO Epidural drape sheet 55x90/2-layer self-adhesive	47783
33050	RD PRO fenestrated ear drape 175x240/2-layer self-adhesive	47783
33051	RD PRO LAP-/spinal drape 225x320/3-layer self-adhesive	47783
33054	RD PRO fenestrated face drape 150x240/2-layer	47783
33055	RD PRO fenestrated drape incision film 120x150/2-layer	47783
33056	RD eyedrape I 150x150 Spunl	47783
33058	RD PRO fenestrated drape variabel 50x75/2-layer self-adhesive	47783
33059	RD PRO fenestrated drape variabel 75x90/2-layer self-adhesive	47783
33060	RD PRO Split Sheet 225x280/2-layer Plus Split=10x100	47783
33062	RD PRO Split Sheet 75x90/2-layer Split=7x30	47783
33064	RD PRO Split Sheet 125x150/2-layer Split=10x45	47783
33065	RD Split Sheet 120x150 PE Split=14x50	47783
33066	RD Split Sheet 150x210 PE Split=14x75	47783
33067	RD PRO Split Sheet 150x200/2-layer Split=10x65	47783
33068	RD PRO Split Sheet 150x200/3-layer Split=10x65	47783
33069	RD PRO Split Sheet 225x260/2-layer Split=10x100	47783
33071	RD PRO Split Sheet 225x260/2-layer Plus Split=10x100	47783

REF	Product name	GMDN
Sterile Products		
33072	RD PRO Split Sheet beidseitig 175x260/2-layer Plus Split=20x100	47783
33073	RD PRO Split Sheet 150x250/2-layer Split=10x80	47783
33077	RD PRO eye drape III 80x80/2-layer	47783
33080	RD PRO Extremity drape H/F 100x175/2-layer	47783
33081	RD PRO Extremity drape H/F 150x180/2-layer	47783
33082	RD PRO Extremity drape H/F 225x300/2-layer Plus	47783
33083	RD PRO Extremity drape 225x320/2-layer	47783
33084	RD PRO Extremity drape 225x320/2-layer Plus	47783
33085	RD PRO Extremity drape 200x300/2-layer	47783
33086	RD PRO Knee arthroscopy drape 225x320/2-layer	47783
33090	RD Back table Cover 120x140	45201
33091	RD Back table Cover 150x190	45201
33092	RD Back table Cover Spezial 150x190	45201
33093	RD Mayo Stand Cover 80x145	45201
33094	RD Mayo Stand Cover Lite 80x145	45201
33095	RD Mayo Stand Cover Spezial 80x145	45021
33100	RD Perineal drape, 20x40/2-layer	47783
33101	RD bottom drape 75x120/2-layer	47783
33102	RD bottom drape pouch 75x100/2-layer	47783
33103	RD arm protector 50	47783
33104	RD leg protector 50x110 2Stk	47783
33105	RD leg protector 75x120 2Stk	47783
33106	RD PRO Orthostock 33x55 incl. 1 film tape	47783
33107	RD PRO Orthostock 33x110 incl. 2 film tapes	47783
33108	RD towels pairs 30x40	45171
33109	RD instrument pouch 1 Kammer 38x40	58967

REF	Product name	GMDN
Sterile Products		
33110	RD instrument pouch 2 Kammern 38x40	58967
33111	RD rectal shield 60x90	47783
33112	RD Control Panel Cover rec 80x145	45021
33113	RD Control Panel Cover round 80x90	45021
33114	RD Image Converter Set/3	45021
33115	RD Image Converter Set/1	45021
33116	RD adhesive tape el 9x50	58484
33118	RD camera cover 16x250	45021
33119	RD camera cover Ri 15x250	45021
33120	RD Control Panel Cover round 90	45021
33121	RD Control Panel Cover round 120	45021
33122	RD Control Panel Cover rec 80x45	45021
33123	RD armrest cover 35x73 2pcs	45021
33124	RD chair cover 75	45021
33125	RD Absorptions-Pads 35x50 2pcs	47783
33126	RD Absorptions-Pad 50x75	47783
33127	RD velcro 2,5x20/24	56630
33128	RD Stock short 24x80	47783
33129	RD Stock medium 24x110	47783
33130	RD Stock large 32x120	47783
33147	RD tube fixation 9x11	58484
33148	RD Epidural drape sheet 75x100/ transp, self-adhesive	47783
33155	RD Image Converter Set/3	45021
33156	RD Instrument pouches 2 chambers 45x25	58967
33160	RD baby drape 90x100	47783
33190	RD PRO OR drape sheet 90x110/2-layer	47783

REF	Product name	GMDN
Sterile Products		
33300	RD PRO Basic-Set mini	33961
33301	RD PRO Basic-Set	33961
33302	RD PRO Basic Set Super	33961
33303	RD PRO Basis-St-Set	33961
33305	RD PRO Uni-Set II	33961
33307	RD PRO Uni-Set I	33961
33309	RD PRO Uni-Set I Super	33961
33310	RD PRO Uni-St-Set I	33961
33313	RD PRO Variable-Split Sheet-Set	47783
33315	RD PRO Set for minor interventions	33961
33317	RD PRO Universal Set II Super	33961
33318	RD PRO Uni-St-Set II	33961
33319	RD PRO Uni-St-Set III	33961
33320	RD PRO LAP-Set I	44096
33321	RD PRO LAP-Set II	44096
33322	RD PRO LAP-Set III	44096
33325	RD PRO Rectum-Set I	33961
33326	RD PRO Rectum-Set II	33961
33330	RD PRO Paediatric-Basic-Set	33961
33343	RD PRO Extremity-Set I	33961
33344	RD PRO Extremity-Set II	33961
33345	RD PRO Extremity-Set III	33961
33347	RD PRO Extremity-Set H/F	33961
33348	RD PRO Knee arthroscopy Set	33961
33349	RD PRO Hand surgery Set	33961
33350	RD PRO Arthroscopy-Set I	33961

REF	Product name	GMDN
Sterile Products		
33351	RD PRO Arthroscopy-Set II	33961
33352	RD PRO Arthroscopy-Set III	33961
33353	RD PRO Arthroscopy-Set IV	33961
33354	RD PRO Shoulderarthroscopy-Set I	33961
33355	RD PRO Shoulderarthroscopy-Set BC	33961
33357	RD PRO Hiparthroscopy-Set	33961
33358	RD PRO Arthroscopy-Set V	33961
33359	RD PRO C-Section drape 1 FL 260/200x335/2-layer	60644
33360	RD PRO Pfannenstiel-Set	33961
33361	RD PRO C-Section-Set I	60644
33362	RD PRO C-Section-Set II	60644
33363	RD PRO Gyn-Cyst-Set	60644
33364	RD PRO Gyn-Set I	60644
33365	RDPRO Gyn-Set II	60644
33366	RD PRO Lithotomie-Set	33961
33368	RD PRO T.U.R.-Set II (Regel/Rule 5)	33961
33370	RD PRO Cranio-Set	33961
33371	RD PRO Headset I	33961
33372	RD PRO Head-Set II	33961
33376	RD PRO T.U.R.-Set I (Regel/Rule 5)	33961
33381	RD PRO Angiography drape 1 150x240/3	33961
33382	RD PRO Angiography drape 2 227x330/3	33961
33383	RD PRO Cardiovascular-Set	61371
33387	RD PRO Hip-Set I	33961
33388	RD PRO Hip-Set II	33961
33389	RD PRO Vertical isolation Set	33961

REF	Product name	GMDN
Sterile Products		
33400	RD Basic-Set mini LRF	33961
33401	RD PRO Basic-Set LRF	33961
33405	RD Uni-Set I LRF	33961
33406	RD PRO Uni-Set I Spezial LRF	33961
33407	RD PRO Uni-Set II LRF	33961
33408	RD Uni-Set II Super LRF	33961
33409	RD PRO Uni-Set II Super LRF	33961
33415	RD PRO Set for minor interventions LRF	33961
33420	RD Laparotomy-Set LRF	33961
33421	RD PRO Zölioskopie-Set I LRF	33961
33422	RD PRO Zölioskopie-Set II LRF	33961
33425	RD Zölioskopie-Gynecology-Set I LRF	60644
33426	RD PRO Zölioskopie-Gynecology-Set II LRF	60644
33430	RD PRO Paediatric-Set LRF	33961
33440	RD PRO Orthopedic-Set LRF	44052
33442	RD Vertical isolation Set LRF	33961
33443	RD PRO Extremity-Set Vst I LRF	33961
33445	RD PRO Extremity-Set Std LRF	33961
33449	RD PRO Extremity-Set bilateral LRF	33961
33450	RD PRO Extremity-Set H/F LRF	33961
33451	RD PRO Knee arthroscopy Set LRF	33961
33452	RD PRO Hand surgery Set LRF	33961
33453	RD PRO Shoulderarthroscopy Set LRF	33961
33454	RD PRO Extremity-Set Vst II LRF	33961
33455	RD PRO Extremity-Set Vst III LRF	33961
33457	RD Delivery-Set I	60644

REF	Product name	GMDN
Sterile Products		
33458	RD Delivery-Set II	60644
33459	RD Delivery-Set III	60644
33460	RD PRO C-Section-Set I LRF	60644
33461	RD C-Section-Set II LRF	60644
33462	RD Zystoskopy-Set LRF	33961
33463	RD PRO Gyn-Set mini LRF	60644
33464	RD PRO Gyn-Set Ab LRF	60644
33465	RD PRO Lithotomie-Set LRF	33961
33467	RD PRO T.U.R.-Set sieve LRF	33961
33468	RD PRO T.U.R.-Set pouch LRF (Regel/Rule 5)	33961
33470	RD PRO Spinal-Set LRF	33961
33471	RD PRO ENT-Set LRF	33961
33472	RD PRO Ear-Set LRF	33961
33473	RD PRO Stomatology-Set LRF	33961
33474	RD PRO Head-Throat-Set LRF	33961
33475	RD PRO Dermatology-Set LRF	33961
33476	RD Strabismus-Set LRF	33961
33477	RD PRO Eye-Set I LRF	45150
33478	RD PRO Eye-Set II LRF	45150
33479	RD PRO Cranio-Set LRF	33961
33480	RD PRO Angiography-Set LRF	33961
33483	RD PRO Pacemaker Set LRF	33961
33487	RD PRO Orthopedic-Set Vst LRF	44052
33489	RD PRO Vertical isolation Set LRF	33961
139937	RD PRO Head-Set II	33961
139938	RD PRO Head-Throat-Set LRF	33961

REF	Product name	GMDN
Sterile Products		
139477	RD PRO Eye-Set I LRF	45150
139478	RD PRO Eye-Set II LRF	45150
33705	RD SMART OR drape sheet 75x90/2-layer	47783
33706	RD SMART OR drape sheet 100x100/2-layer	47783
33707	RD SMART OR drape sheet 150x150/2-layer	47783
33716	RD SMART adhesive drape 75x90/2-layer	47783
33717	RD SMART adhesive drape 140x240/2-layer	47783
33718	RD SMART adhesive drape 175x170/2-layer	47783
33738	RD SMART Vertical drape 230x320	47783
33740	RD SMART fenestrated drape 50x60/2-layer self-adhesive	47783
33741	RD SMART fenestrated drape 120x150/2-layer self-adhesive	47783
33742	RD SMART fenestrated drape variable 75x90/2-layer self-adhesive 2 pieces	47783
33760	RD SMART Split Sheet 200x260/2-layer Split=10x80	47783
33770	RD SMART Orthostock 33x55 incl. 1 film tape	47783
33771	RD SMART Orthostock 33x110 incl. 2 film tapes	47783
33775	RD Universal fluid collection pouch	56731
33780	RD SMART Extremity drape Hand/Foot 200x300/2-layer	47783
33793	RD Mayo Stand Cover 80x145	45021
33801	RD SMART Universal-Set	33961
33810	RD SMART Universal Split sheet Set	33961
33825	RD SMART Abdominal-Perineal-Set	33961
33841	RD SMART Orthopaedic-Set	33961
33844	RD SMART Extremity-Set	33961
33851	RD SMART Arthroscopy-Set	33961
33861	RD SMART C-Section-Set	60644
33863	RD SMART Cystoscopy-Set	33961

REF	Product name	GMDN
Sterile Products		
33866	RD SMART Gynaecology-Urology-Set	60644
33867	RD SMART TUR-Set (Regel/Rule 5)	33961
33901	RD SMART Universal-Set	33961
33902	RD SMART Basis-Set	33961
33909	RD SMART Universal-Set Super	33961
33915	RD SMART Set für Kleineingriffe I	33961
33916	RD SMART Set für Kleineingriffe II	33961
33918	RD PRO Universal split sheet set IV	33961
33925	RD SMART Zölioskopie-Gynäkologie-Set	60644
33952	RD SMART Handchirurgie-Set	33961
139952	RD SMART Handchirurgie-Set	33961
33958	RD SMART Entbindungs-Set I	33961
33959	RD SMART Entbindungs-Set II	33961
33963	RD SMART Cystoscopy-Set	33961
34053	RD SMART Orthostock 33x55 incl. 1 film tape	47783
34054	RD SMART Orthostock 33x110 incl. 2 film tapes	47783
34096	RD Back table Cover Special XL 200x250	45021
34242	RD Basic Set Super V	33961
34245	RD Rectum set V	33961
34248	RD Universal split sheet set V	33961
34249	RD Universal Set Super V	33961
34252	RD Basic Set Super S	33961
34255	RD Rectum set S	33961
34258	RD Universal split sheet set S	33961
34259	RD Universal Set Super S	33961
34262	RD Basic Set Super K	33961

REF	Product name	GMDN
Sterile Products		
34265	RD Rectum set K	33961
34268	RD Universal split sheet set K	33961
34269	RD Universal Set Super K	33961
34665	RD camera drape variant L, rev. folded 13 x 250 cm	45021
34915	RD SMART Set for minor interventions I	33961
34916	RD SMART Set for minor interventions II	33961
105945	RD camera drape variant B, rev. folded 13 x 250 cm	45021
137038	RD PRO Vertical Drape, 250x330cm	47783
153704	RD SMART OR drape sheet 75x75/2-layer	47783
153705	RD SMART OP-Adt 75x90/2	47783
153706	RD SMART OP-Adt 100x100/2	47783
153740	RD SMART Lochtuch 50x60/2 sk	47783
153742	RD SMART Lochtuch variabel 75x90/2 sk	47783
153770	RD SMART Orthostock 33x55 inkl. 1Fks	47783
153771	RD SMART Orthostock 33x110 inkl. 2Fks	47783
138128	RD Camera Drape, 16x250cm	12535
160056	RD PRO Augentuch I 150x150 Spunl 3 lagig	47783
138101	RD Unterlegtuch 75x120 100/2-lagig	47783