

EU Declaration of Conformity

As our company, we declare under our sole responsibility that the devices specified in this EU declaration of conformity comply with the Medical Device Regulation (EU) 2017/745 and that the requirements specified in the regulation and relevant standards for these devices are fulfilled.

SRN (Single Registration Number)

TR-MF-000039333

Device Name

Rigid Endoscope Device

EMDN Code

Z120204

Basic UDI-DI

868376217744436X

Device Risk Class / Classification Rule

Annex VIII Class IIa / Rule 5

Conformity Assessment Procedure

Annex IX Part I & III

Notified Body Name-Address

KIWA BELGELENDİRME HİZMETLERİ A.Ş. (No: 1984)

İ.T.O.S.B 9. Cadde No: 15

Tepeören Mevkii PK 34959

Tuzla İstanbul

EC Certificate No

1984-MDD-21-833

Applicable EU Directives

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

Applicable StandardsEN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 14971:2019, ISO/TR 24971:2020,
EN ISO 20417:2021, EN ISO 17665-1:2006, ISO 8600-1:2015, ISO 8600-2:2015, ISO 8600-6:2020,
ISO 8600-7:2012, EN ISO 11737-2:2020, EN 62366-1:2015+A1:2020, EN ISO 10993-1:2020**ON BEHALF OF MANUFACTURER****Name – Title** : Amir HAN – Quality Management Representative**Date-Place** : 03.12.2024 / İSTANBUL – TÜRKİYE**Signature-Stamp** :QAMARA ENDOSKOPI MEDİKAL SİSTEMLER SAN. VE TİC. LTD. ŞTİ.
İkitelli OSB, Giyim Sanatkarları Sitesi, 3. Ada B Blok Kat 5 No 518
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1 / 6

ANNEX 1 – PRODUCT LIST

No	PRODUCT NAME	PRODUCT CODE	Diameter (mm)	Length (mm)	Angle
1	Artro-rinoskop	KS191100	1,9	110	0°
2	Artro-rinoskop	KS191130	1,9	110	30°
3	Artro-rinoskop	RW191200	1,9	120	0°
4	Artro-rinoskop	RW191230	1,9	120	30°
5	Artro-rinoskop	RW246000	2,4	60	0°
6	Artro-rinoskop	RW246030	2,4	60	30°
7	Artro-rinoskop	ST247200	2,4	72,5	0°
8	Artro-rinoskop	ST247230	2,4	72,5	30°
9	Artro-rinoskop	LT256300	2,5	63	0°
10	Artro-rinoskop	LT256330	2,5	63	30°
11	Artro-rinoskop	KS276000	2,7	60	0°
12	Artro-rinoskop	KS276030	2,7	60	30°
13	Artro-rinoskop	RW276000	2,7	60	0°
14	Artro-rinoskop	RW276030	2,7	60	30°
15	Artro-rinoskop	DY276000	2,7	58,5	0°
16	Artro-rinoskop	DY276030	2,7	58,5	30°
17	Artro-rinoskop	RW271000	2,7	102,2	0°
18	Artro-rinoskop	RW271030	2,7	102,2	30°
19	Artro-rinoskop	DY271100	2,7	110	0°
20	Artro-rinoskop	DY271130	2,7	110	30°
21	Artro-rinoskop	KS271100	2,7	110	0°
22	Artro-rinoskop	KS271130	2,7	110	30°
23	Artro-rinoskop	ST271200	2,7	120,5	0°
24	Artro-rinoskop	ST271230	2,7	120,5	30°
25	Artro-rinoskop	OL271430	2,7	142	30°
26	Artro-rinoskop	OL271600	2,7	160	0°
27	Artro-rinoskop	OL271630	2,7	160	30°
28	Artro-rinoskop	KS271700	2,7	175	0°
29	Artro-rinoskop	KS271730	2,7	175	30°
30	Artro-rinoskop	KS271770	2,7	175	70°
31	Artro-rinoskop	KS271800	2,7	185	0°
32	Artro-rinoskop	KS271830	2,7	185	30°
33	Artro-rinoskop	KS291400	2,9	140	0°
34	Artro-rinoskop	KS291430	2,9	140	30°
35	Artro-rinoskop	LT291500	2,9	152	0°
36	Artro-rinoskop	LT291530	2,9	152	30°
37	Artro-rinoskop	LT291545	2,9	152	45°

38	Artro-rinoskop	LT291570	2,9	152	70°
39	Artro-rinoskop	KS406000	4	60	0°
40	Artro-rinoskop	KS406030	4	60	30°
41	Artro-rinoskop	ST401400	4	141,6	0°
42	Artro-rinoskop	ST401430	4	141,6	30°
43	Artro-rinoskop	AR401500	4	156	0°
44	Artro-rinoskop	AR401530	4	156	30°
45	Artro-rinoskop	DY401500	4	157	0°
46	Artro-rinoskop	DY401530	4	157	30°
47	Artro-rinoskop	DY401545	4	157	45°
48	Artro-rinoskop	DY401570	4	157	70°
49	Artro-rinoskop	OL401500	4	158,5	0°
50	Artro-rinoskop	OL401530	4	158,5	30°
51	Artro-rinoskop	ST401630	4	166,5	30°
52	Artro-rinoskop	ST401600	4	167,5	0°
53	Artro-rinoskop	LT401700	4	170	0°
54	Artro-rinoskop	LT401730	4	170	30°
55	Artro-rinoskop	RW401700	4	170	0°
56	Artro-rinoskop	RW401725	4	170	30°
57	Artro-rinoskop	RW401745	4	170	45°
58	Artro-rinoskop	RW401770	4	170	70°
59	Artro-rinoskop	RW401790	4	170	90°
60	Artro-rinoskop	KS401700	4	175	0°
61	Artro-rinoskop	KS401725	4	175	30°
62	Artro-rinoskop	KS40173090	4	175	30°
63	Artro-rinoskop	KS401745	4	175	45°
64	Artro-rinoskop	KS401760	4	175	70°
65	Artro-rinoskop	KS401790	4	175	90°
66	Larengoskop	KS581960	5,8	190	70°
67	Larengoskop	KS581990	5,8	190	90°
68	Larengoskop	KS801970	8	190	70°
69	Larengoskop	KS801990	8	190	90°
70	Larengoskop	KS101970	10	190	70°
71	Larengoskop	KS101990	10	190	90°
UROLOGY / GYNECOLOGY					
	PRODUCT NAME	PRODUCT CODE	Diameter (mm)	Length (mm)	Angle
72	Sisteskop pediatrik	RW191700	1,9	178	0°
73	Sisteskop pediatrik	RW191730	1,9	178	30°
74	Sisteskop pediatrik	KS211800	2,1	186	0°
75	Sisteskop pediatrik	KS211830	2,1	186	30°

76	Histero-sisteskop	RW273112	2,7	310	12°
77	Histero-sisteskop	RW2731000	2,7	310	0°
78	Histero-sisteskop	RW273125	2,7	310	25
79	Histero-sisteskop	ST293000	2,9	301,2	0°
80	Histero-sisteskop	ST293012	2,9	301,2	12°
81	Histero-sisteskop	ST293030	2,9	301,2	30°
82	Histero-sisteskop	KS293000	2,9	302	0°
83	Histero-sisteskop	KS293012	2,9	302	12°
84	Histero-sisteskop	KS293030	2,9	302	30°
85	Histero-sisteskop	OL302800	3	282	0°
86	Histero-sisteskop	OL302812	3	282	12°
87	Histero-sisteskop	OL302830	3	282	30°
88	Histero-sisteskop	RW333000	3,3	300	0°
89	Histero-sisteskop	RW333012	3,3	300	12°
90	Histero-sisteskop	RW333030	3,3	300	30°
91	Histero-sisteskop	OL402800	4	280	0°
92	Histero-sisteskop	OL402812	4	280	12°
93	Histero-sisteskop	OL402825	4	282	30°
94	Histero-sisteskop	OL402870	4	284	70°
95	Histero-sisteskop	RW403000	4	300	0°
96	Histero-sisteskop	RW403012	4	300	12°
97	Histero-sisteskop	RW403025	4	300	30°
98	Histero-sisteskop	RW403070	4	300	70°
99	Histero-sisteskop	ST403000	4	300	0°
100	Histero-sisteskop	ST403012	4	300	12°
101	Histero-sisteskop	ST403030	4	300	30°
102	Histero-sisteskop	ST403070	4	300	70°
103	Histero-sisteskop	AC403000	4	300	0°
104	Histero-sisteskop	AC403012	4	300	12°
105	Histero-sisteskop	AC403030	4	300	30°
106	Histero-sisteskop	KS403000	4	302	0°
107	Histero-sisteskop	KS403012	4	302	12°
108	Histero-sisteskop	KS403030	4	302	30°
109	Histero-sisteskop	KS403060	4	302	70°
URETHROSCOPY / NEPHROSCOPY					
	PRODUCT NAME	PRODUCT CODE	Diameter (mm)	Length (mm)	Angle
110	Sistoureteroskop, 6 Fr. Channel	KS95111360	9.5/11 Fr	130	6°
111	Nefroskop, paralel okuler	RW271925P	27 Fr	195	25°
112	Nefroskop, paralel okuler	RW202012P	20.8 Fr	205	12°
113	Nefroskop, paralel okuler	RW242020P	24 Fr	205	20°

114	Mini-Nefroskop, açılı okuler	OL122212A	12 Fr	225	12°
115	Nefroskop, açılı okuler	OL222330A	22 Fr	230	30°
116	Nefroskop, paralel okuler	KS182000P	18 Fr	200	6°
117	Nefroskop, açılı okuler	KS182000A	18 Fr	200	6°
118	Nefroskop, paralel okuler	KS182600P	18 Fr	263	6°
119	Nefroskop, açılı okuler	KS182600A	18 Fr	263	6°
120	Ureteroskop, 4.2 Fr. Channel	OL64783370A	6.4/7.8 Fr	330	7°
121	Ureteroskop, 4.2 Fr. Channel	OL64783370B	6.4/7.8 Fr	330	7°
122	Ureteroskop 4.8 Fr. Channel	KS70993460	7/9.9 Fr	340	6°
123	Ureteroskop 5 Fr. Channel	KS80123460	8/12 Fr	340	6°
124	Ureteroskop 4.8 Fr. Channel	KS70994360	7/9.9 Fr	430	6°
125	Ureteroskop 5 Fr. Channel	KS80124360	8/12 Fr	430	6°
126	Ureteroskop, 4.2 Fr. Channel	OL64784370A	6.4/7.8 Fr	430	7°
127	Ureteroskop, 4.2 Fr. Channel	OL64784370B	6.4/7.8 Fr	430	7°
128	Ureteroskop, 6.4 Fr. Channel	OL86984370C	8.6/9.8 Fr	430	7°
129	Ureteroskop, 6.2 Fr. Channel	RW80984312	8 / 9.8 Fr	430	10°
130	Ureteroskop, 4,6 Fr. Channel	RW60754350	6 / 7.5 Fr	430	5°
ABDOMEN/CHEST SURGERY					
	PRODUCT NAME	PRODUCT CODE	Diameter (mm)	Length (mm)	Angle
131	Bronkoskop	RW273100	2,7	310	0°
132	Bronkoskop	KS284400	2,8	440	0°
133	Bronkoskop	KS293600	2,9	362	0°
134	Bronkoskop	KS293630	2,9	362	30°
135	Bronkoskop	RW343800	3,4	380	0°
136	Bronkoskop	RW343860	3,4	380	60°
137	Bronkoskop	RW343890	3,4	380	90°
138	Videomediastinoskop	KS401430	4	140	30°
139	Videomediastinoskop	KS401600	4	160	0°
140	Bronkoskop	RW405200	4	526,5	0°
141	Bronkoskop	RW405230	4	526,5	30°
142	Bronkoskop	KS454900	4,5	490	0°
143	Bronkoskop	KS454930	4,5	490	30°
144	Laporoskop	KS502400	5	240	0°
145	Laporoskop	KS502430	5	240	30°
146	Laporo-torakoskop	KS502900	5	290	0°
147	Laporo-torakoskop	KS502930	5	290	30°
148	Laporo-torakoskop	KS502945	5	290	45°
149	Laporoskop	RW533000	5,3	300	0°
150	Laporoskop	RW533030	5,3	300	30°
151	Laporoskop	RW533050	5,3	300	50°

152	Bronkoskop	KS554900	5,5	490	0°
153	Bronkoskop	KS554930	5,5	490	30°
154	Osofagoskop	RW554900	5,5	495	0°
155	Osofagoskop	RW554930	5,5	495	30°
156	Osofagoskop	RW554960	5,5	495	60°
157	Osofagoskop	RW554990	5,5	495	90°
158	Osofagoskop	RW5549110	5,5	495	110°
159	Laporoskop	KS653000	6,5	302	0°
160	Laporoskop	KS653030	6,5	302	30°
161	Laporoskop	KS103300	10	313	0°
162	Laporoskop	KS103330	10	313	30°
163	Laporoskop	KS103345	10	313	45°
164	Bariatrik Laporoskop	KS104200	10	420	0°
165	Bariatrik Laporoskop	KS104230	10	420	30°
166	Bariatrik Laporoskop	KS104245	10	420	45°
NEUROLOGY					
	PRODUCT NAME	PRODUCT CODE	Diameter (mm)	Length (mm)	Angle
167	Spinendoskop, Açılı oküler, ID 3,1	RW311225	15 Fr	124	25°
168	Neroendoskop, Dik oküler	AE401500	4	150	0°
169	Neroendoskop, Dik oküler	AE401530	4	150	30°
170	Neroendoskop, Dik oküler	AE401570	4	150	70°
171	Spinendoskop, Açılı oküler, ID 3,1	RW311625	15 Fr	165	25°
172	Spinendoskop, Açılı oküler, ID 4,1	RW411625	18 Fr	165	25°
173	Spinendoskop, Açılı oküler, ID 5,6	RW561625	21,6 Fr	165	25°
174	Neroendoskop, Dik oküler	AE271800	2,7	180	0°
175	Neroendoskop, Dik oküler	AE271830	2,7	180	30°
176	Neroendoskop, Açılı oküler	KS611806	6,1	180	6°
177	Spinendoskop, Açılı oküler, ID 3,1	RW312025	15 Fr	205	25°
178	Spinendoskop, Açılı oküler, ID 4,1	RW412025	18 Fr	205	25°