



EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/ EEC

CONFORMITY CERTIFICATE

Company : DLR MEDİKAL SAN. VE DIŞ TİC. LTD.ŞTİ.

Authorized Person/Title : HÜSEYİN HAMZA /GENERAL MANAGER

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We Hereby declare that for our following products;

STONE BASKET – Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standarts below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
EN ISO 14971: 2019 EN ISO 10993-1:2011 EN 62366-1:2015
EN ISO 10993-5:2010 EN ISO 10993-12:2013 EN 1618:2000
EN ISO 10993-7:2015 EN ISO 10993-11:2018 EN ISO 11135:2014
EN 975:2015 EN ISO 15223-1:2016 EN ISO 11737-1:2018

Reference Number	Product name/Models	GMDN Code
7743090	LUMINA STONE BASKET 3.0 FR. 4 WIRE 90 CM (H)	35808
7744090	LUMINA STONE BASKET 4.0 FR. 4 WIRE 90 CM (H)	35808

7753090	LUMINA STONE BASKET 3.0 FR. 5 WIRE 90 CM (H)	35808
7754090	LUMINA STONE BASKET 4.0 FR. 5 WIRE 90 CM (H)	35808
7743011	LUMINA STONE BASKET 3.0 FR. 4 WIRE 110 CM (H)	35808
7744011	LUMINA STONE BASKET 4.0 FR. 4 WIRE 110 CM (H)	35808
7753011	LUMINA STONE BASKET 3.0 FR. 5 WIRE 110 CM (H)	35808
7754011	LUMINA STONE BASKET 4.0 FR. 5 WIRE 110 CM (H)	35808
7743013	LUMINA STONE BASKET 3.0 FR. 4 WIRE 130 CM (H)	35808
7744013	LUMINA STONE BASKET 4.0 FR. 4 WIRE 130 CM (H)	35808
7753013	LUMINA STONE BASKET 3.0 FR. 5 WIRE 130 CM (H)	35808
7754013	LUMINA STONE BASKET 4.0 FR. 5 WIRE 130 CM (H)	35808
7843090	LUMINA STONE BASKET 3.0 FR. 4 WIRE 90 CM (S)	35808
7844090	LUMINA STONE BASKET 4.0 FR. 4 WIRE 90 CM (S)	35808
7853090	LUMINA STONE BASKET 3.0 FR. 5 WIRE 90 CM (S)	35808
7854090	LUMINA STONE BASKET 4.0 FR. 5 WIRE 90 CM (S)	35808
7843011	LUMINA STONE BASKET 3.0 FR. 4 WIRE 110 CM (S)	35808
7844011	LUMINA STONE BASKET 4.0 FR. 4 WIRE 110 CM (S)	35808
7853011	LUMINA STONE BASKET 3.0 FR. 5 WIRE 110 CM (S)	35808
7854011	LUMINA STONE BASKET 4.0 FR. 5 WIRE 110 CM (S)	35808
7843013	LUMINA STONE BASKET 3.0 FR. 4 WIRE 130 CM (S)	35808
7844013	LUMINA STONE BASKET 4.0 FR. 4 WIRE 130 CM (S)	35808
7853013	LUMINA STONE BASKET 3.0 FR. 5 WIRE 130 CM (S)	35808
7854013	LUMINA STONE BASKET 4.0 FR. 5 WIRE 130 CM (S)	35808
7943090	LUMINA STONE BASKET 3.0 FR. 4 WIRE 90 CM (N)	35808
7944090	LUMINA STONE BASKET 4.0 FR. 4 WIRE 90 CM (N)	35808
7953090	LUMINA STONE BASKET 3.0 FR. 5 WIRE 90 CM (N)	35808
7954090	LUMINA STONE BASKET 4.0 FR. 5 WIRE 90 CM (N)	35808
7943011	LUMINA STONE BASKET 3.0 FR. 4 WIRE 110 CM (N)	35808
7944011	LUMINA STONE BASKET 4.0 FR. 4 WIRE 110 CM (N)	35808
7953011	LUMINA STONE BASKET 3.0 FR. 5 WIRE 110 CM (N)	35808
7954011	LUMINA STONE BASKET 4.0 FR. 5 WIRE 110 CM (N)	35808
7943013	LUMINA STONE BASKET 3.0 FR. 4 WIRE 130 CM (N)	35808
7944013	LUMINA STONE BASKET 4.0 FR. 4 WIRE 130 CM (N)	35808
7953013	LUMINA STONE BASKET 3.0 FR. 5 WIRE 130 CM (N)	35808
7954013	LUMINA STONE BASKET 4.0 FR. 5 WIRE 130 CM (N)	35808
7043090	LUMINA STONE BASKET 3.0 FR. 4 WIRE 90 CM (N-ZERO TIP)	35808
7053090	LUMINA STONE BASKET 3.0 FR. 5 WIRE 90 CM (N-ZERO TIP)	35808
7043011	LUMINA STONE BASKET 3.0 FR. 4 WIRE 110 CM (N-ZERO TIP)	35808

7053011	LUMINA STONE BASKET 3.0 FR. 5 WIRE 110 CM (N-ZERO TIP)	35808
7043013	LUMINA STONE BASKET 3.0 FR. 4 WIRE 130 CM (N-ZERO TIP)	35808
7053013	LUMINA STONE BASKET 3.0 FR. 5 WIRE 130 CM (N-ZERO TIP)	35808
7133090	LUMINA STONE GRESPER 3.0 FR. 90 CM (TRIPRONG)	35808
7133012	LUMINA STONE GRESPER 3.0 FR. 120 CM (TRIPRONG)	35808
7131238	LUMINA PCN BASKET (PERK) 12.0 FR 38 CM	35808
7131037	LUMINA PERK BASKET (PCNL) 10 FR 37 CM	35808
7131038	LUMINA PERK BASKET (PCNL) 10 FR 38 CM	35808
7041512	LUMINA STONE BASKET 1.5 FR. 4 WIRE 120 CM NITINOL (Z)	35808
7041712	LUMINA STONE BASKET 1.7 FR. 4 WIRE 120 CM NITINOL (Z)	35808
7041912	LUMINA STONE BASKET 1.9 FR. 4 WIRE 120 CM NITINOL (Z)	35808
7042212	LUMINA STONE BASKET 2.2 FR. 4 WIRE 120 CM NITINOL (Z)	35808
7042412	LUMINA STONE BASKET 2.4 FR. 4 WIRE 120 CM NITINOL (Z)	35808
7063012-7	STONE STOP - Nitinol Stone retrieval coil 3Fr 120cm 7mm	35808
7063012-10	STONE STOP - Nitinol Stone retrieval coil 3Fr 120cm 10mm	35808
7063013-9	3-Bow Nitinol Stone Extractor 2.2Fr 120cm 9mm opening 3 wires	35808
7063014-9	3-Bow Nitinol Stone Extractor 1.9Fr 120cm 9mm opening 3 wires	35808

NEEDLES – Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
EN ISO 14971: 2019 EN ISO 10993-1:2009/AC:2010 EN 556-1:2009
EN ISO 10993-5:2009 EN ISO 10993-12:2012 EN 80369-7:2017
EN ISO 10993-7:2008/AC:2009 EN ISO 10993-11:2009 EN 62366-1:2015
EN ISO 11135-1:2007 EN ISO 15223-1:2016 EN ISO 11737-1:2018
EN 1041+A1:2014 ISO 7864:2016 EN ISO 6009:2016
ISO 14644-1: 2016 EN ISO 14644-2:2016 EN ISO 14155:2012
ISO 11140-1:2015 ISO 11138-2:2017 EN ISO 14937:2011

I.P. NEEDLE(Initial puncture needle)

Reference Number	Product name/Models	GMDN Code
2220010	I.P. NEEDLE 18G 23 CM (TWO PART)	32337
2220011	I.P. NEEDLE 18G 15 CM (TWO PART)	32337
2220012	I.P. NEEDLE 18G 23 CM (THREE PART)	32337
2220013	I.P. NEEDLE 18G 15 CM (THREE PART)	32337
2220014	I.P. NEEDLE 18G 23 CM (TWO PART)STEEL	32337
2220015	I.P. NEEDLE 18G 15 CM (TWO PART)STEEL	32337
2220016	I.P. NEEDLE 18G 23 CM (THREE PART)STEEL	32337
2220017	I.P. NEEDLE 18G 15 CM (THREE PART)	32337
2220018	IP NEEDLE(2 PART) 18 G 20 CM	32337
2220019	IP NEEDLE(3 PART) 18 G 20 CM	32337

CHIBA NEEDLE

Reference Number	Product name/Models	GMDN Code
4100010	CHIBA NEEDLE 22 G X 15 CM	32337
4100011	CHIBA NEEDLE 22 G X 20 CM	32337
4100012	CHIBA NEEDLE 22 G X 22 CM	32337
4100013	CHIBA NEEDLE 23 G X 15 CM	32337
4100014	CHIBA NEEDLE 23 G X 20 CM	32337
4100015	CHIBA NEEDLE 23 G X 22 CM	32337
4100016	CHIBA NEEDLE 18 G 15 CM	32337
4100017	CHIBA NEEDLE 18 G 20 CM	32337
4100018	CHIBA NEEDLE 20 G 15 CM	32337

BIOPSY GUN

Reference Number	Product name/Models	GMDN Code
4110010	BIOPSY GUN 16 G 09 CM	12734
4110011	BIOPSY GUN 16 G 15 CM	12734
4110012	BIOPSY GUN 16 G 16 CM	12734
4110013	BIOPSY GUN 16 G 18 CM	12734
4110014	BIOPSY GUN 16 G 20 CM	12734
4110015	BIOPSY GUN 16 G 23 CM	12734
4110016	BIOPSY GUN 18 G 09 CM	12734
4110017	BIOPSY GUN 18 G 15 CM	12734
4110018	BIOPSY GUN 18 G 16 CM	12734
4110019	BIOPSY GUN 18 G 20 CM	12734
4110020	BIOPSY GUN 18 G 22 CM	12734
4110021	BIOPSY GUN 18 G 23 CM	12734
4110022	BIOPSY GUN 20 G 15 CM	12734
4110023	BIOPSY GUN 20 G 16 CM	12734

4110024	BIOPSY GUN 20 G 22 CM	12734
4110025	BIOPSY GUN 18 G 15 CM (CO-AXIAL)	12734
4110026	BIOPSY GUN 18 G 16 CM (CO-AXIAL)	12734
4110027	BIOPSY GUN 18 G 22 CM (CO-AXIAL)	12734

GUIDEWIRES-Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standarts below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
 EN ISO 14971: 2019 EN ISO 10993- 1:2009 EN ISO 10993- 5:2009
 ISO 10993- 7:2008 EN ISO 10993-10:2013 EN ISO 10993-12:2012
 EN ISO 15223-1:2016 ISO 14644-1: 2015 EN ISO 14644-2:2015
 BS EN ISO 11737-1:2018 BS EN 556-1:2001 EN1041:2008+A1:2013
 BS EN ISO 11070: 2014 + A1: 2018 ASTM F1929 - 15 ASTM F 2096 - 11
 ASTM D 3078-02(2013) ASTM F 1886 / F1886M - 16 ASTM F 1980-16
 ASTM F88 / F88M - 15

Reference Number	Product name/Models	GMDN Code
3001815	RODRAM PTFE GUIDE WIRE 0.018"X150 CM. (ST)	45623
3002515	RODRAM PTFE GUIDE WIRE 0.025"X150 CM. (ST)	45623
3002815	RODRAM PTFE GUIDE WIRE 0.028"X150 CM. (ST)	45623
3003215	RODRAM PTFE GUIDE WIRE 0.032"X150 CM. (ST)	45623
3003515	RODRAM PTFE GUIDE WIRE 0.035"X150 CM. (ST)	45623
3003815	RODRAM PTFE GUIDE WIRE 0.038"X150 CM. (ST)	45623
3011815	RODRAM PTFE GUIDE WIRE 0.018"X150 CM. (JT)	45623
3012515	RODRAM PTFE GUIDE WIRE 0.025"X150 CM. (JT)	45623
3012815	RODRAM PTFE GUIDE WIRE 0.028"X150 CM. (JT)	45623
3013215	RODRAM PTFE GUIDE WIRE 0.032"X150 CM. (JT)	45623
3013515	RODRAM PTFE GUIDE WIRE 0.035"X150 CM. (JT)	45623
3013815	RODRAM PTFE GUIDE WIRE 0.038"X150 CM. (JT)	45623
3021815	Z-WIRE GUIDE WIRE 0,018"X150 CM. (ST)	45623
3022515	Z-WIRE GUIDE WIRE 0,025"X150 CM. (ST)	45623
3022815	Z-WIRE GUIDE WIRE 0,028"X150 CM. (ST)	45623

3023215	Z-WIRE GUIDE WIRE 0,032"X150 CM. (ST)	45623
3023515	Z-WIRE GUIDE WIRE 0,035"X150 CM. (ST)	45623
3023815	Z-WIRE GUIDE WIRE 0,038"X150 CM. (ST)	45623
3031815	Z-WIRE GUIDE WIRE 0,018"X150 CM. (JT)	45623
3032515	Z-WIRE GUIDE WIRE 0,025"X150 CM. (JT)	45623
3032815	Z-WIRE GUIDE WIRE 0,028"X150 CM. (JT)	45623
3033215	Z-WIRE GUIDE WIRE 0,032"X150 CM. (JT)	45623
3033515	Z-WIRE GUIDE WIRE 0,035"X150 CM. (JT)	45623
3033815	Z-WIRE GUIDE WIRE 0,038"X150 CM. (JT)	45623
3041815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.018"X150 CM. (ST)	45623
3042515	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.025"X150 CM. (ST)	45623
3042815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.028"X150 CM. (ST)	45623
3043215	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.032"X150 CM. (ST)	45623
3043515	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.035"X150 CM. (ST)	45623
3043815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.038"X150 CM. (ST)	45623
3043518	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.035"X180 CM. (ST)	45623
3043818	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.038"X180 CM. (ST)	45623
3051815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.018"X150 CM. (ANG)	45623
3052515	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.025"X150 CM. (ANG)	45623
3052815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.028"X150 CM. (ANG)	45623
3053215	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.032"X150 CM. (ANG)	45623
3053515	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.035"X150 CM. (ANG)	45623
3053815	SUPERGLIDE HYDROPHILIC GUIDE WIRE 0.038"X150 CM. (ANG)	45623

URETERAL CATHETERS-Class- IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
 EN ISO 14971: 2013 EN ISO 10993-1:2011 EN ISO 10993-5:2010
 ISO 10993- 7:2010 EN ISO 10993-10:2014 EN ISO 10993-12:2013
 EN ISO 15223-1:2016 ISO 14644-1:2016 ISO 14644-2:2016
 EN ISO 11737-1:2018 EN 1041+A1:2014 EN 556-1:2009
 EN ISO 11070+A1: 2018 TS EN 1618:2000 EN ISO 10993-11:2018
 EN ISO 11135:2014 EN ISO 11140-1:2014 EN ISO 11737-2:2009
 ISO 80369-7:2017 ASTM F1929 – 15 ASTM F 2096 – 11
 ASTM D 3078-02(2013) ASTM F 1886 / F1886M – 16 ASTM F 1980-16
 ASTM F88 / F88M – 15 ASTM D1938 – 14:2014 ASTM D638 – 14:2014

Reference Number	Product name/Models	GMDN Code
1103070	InROD URETERAL CATHETER 3.0 FR. 70 CM (CE-P)	34926
1104070	InROD URETERAL CATHETER 4.0 FR. 70 CM (CE-P)	34926
1105070	InROD URETERAL CATHETER 5.0 FR. 70 CM (CE-P)	34926
1106070	InROD URETERAL CATHETER 6.0 FR. 70 CM (CE-P)	34926
1107070	InROD URETERAL CATHETER 7.0 FR. 70 CM (CE-P)	34926
1108070	InROD URETERAL CATHETER 8.0 FR. 70 CM (CE-P)	34926
1113070	InROD URETERAL CATHETER 3.0 FR. 70 CM (OE-P)	34926
1114070	InROD URETERAL CATHETER 4.0 FR. 70 CM (OE-P)	34926
1115070	InROD URETERAL CATHETER 5.0 FR. 70 CM (OE-P)	34926
1116070	InROD URETERAL CATHETER 6.0 FR. 70 CM (OE-P)	34926
1117070	InROD URETERAL CATHETER 7.0 FR. 70 CM (OE-P)	34926
1118070	InROD URETERAL CATHETER 8.0 FR. 70 CM (OE-P)	34926
1123070	InROD URETERAL CATHETER 3.0 FR. 70 CM (CONE TIP-P)	34926
1124070	InROD URETERAL CATHETER 4.0 FR. 70 CM (CONE TIP-P)	34926
1125070	InROD URETERAL CATHETER 5.0 FR. 70 CM (CONE TIP-P)	34926
1126070	InROD URETERAL CATHETER 6.0 FR. 70 CM (CONE TIP-P)	34926
1127070	InROD URETERAL CATHETER 7.0 FR. 70 CM (CONE TIP-P)	34926
1128070	InROD URETERAL CATHETER 8.0 FR. 70 CM (CONE TIP-P)	34926
1130850	InROD URETERAL CATHETER 8.0 FR. 50 CM	34926
1131050	InROD URETERAL CATHETER 10 FR. 50 CM	34926
1131250	InROD URETERAL CATHETER 12 FR. 50 CM	34926

TURP LOOPS / CLASS IIb

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
 EN ISO 14971: 2019 EN ISO 10993- 1:2011 EN ISO 10993- 5:2010
 ISO 10993- 7:2010 EN ISO 10993-10:2014 EN ISO 10993-12:2013
 EN ISO 15223-1:2016 ISO 14644-1: 2016 EN ISO 14644-2:2016
 BS EN ISO 11737-1:2018 BS EN 556-1:2009 EN1041+A1:2014
 BS EN ISO 11070: 2015 ASTM F1929 - 15 ASTM F 2096 - 11
 ASTM D 3078-02(2013) ASTM F 1886 / F1886M - 16 ASTM F 1980-16
 ASTM F88 / F88M - 15 ASTM F1140 / F1140M - 13 BS EN ISO 11135:2014
 EN ISO 10993-3:2015 EN ISO 10993-11:2018 EN ISO 10993-17:2013
 EN ISO 10993-18:2013 EN ISO 11135:2014 IEC 60601-1-6:2006
 IEC 60601-2-18:2016 EN IEC 60601-2-2:2018 ASTM D 638-14
 ASTM D882-18 ASTM D 1938-14 ISO 80369-7:2017

NB-MED/2.12/Rec1 MEDDEV. 2.7.1 REV 4

Reference Number	Product name/Models	GMDN Code
2210110	CUTTING LOOP (SS) STORZ 24CH	62061
2210111	CUTTING LOOP (SS) STORZ 27CH	62061
2210112	CUTTING LOOP (SS) WOLF 24CH	62061
2210113	CUTTING LOOP (SS) WOLF 27CH	62061
2210114	CUTTING LOOP (DS) STORZ 24CH	62061
2210115	CUTTING LOOP (DS) STORZ 27CH	62061
2210116	CUTTING LOOP (DS) WOLF 24CH	62061
2210117	CUTTING LOOP (DS) WOLF 27CH	62061
2210118	COLD KNIFE (SS) STORZ	62061
2210119	COLD KNIFE (SS) SERAGATTED	62061
2210120	COLD KNIFE (SS) HALF MOON	62061
2210121	COLD KNIFE (SS) STRAIGHT	62061
2210122	COLD KNIFE (DS) STORZ	62061
2210123	COLD KNIFE (DS) SERAGATTED	62061
2210124	COLD KNIFE (DS) HALF MOON	62061
2210125	COLD KNIFE (DS) STRAIGHT	62061
2210126	ROOLER LOOP (DS) 3MM (PLAIN)	62061

2210127	ROOLER LOOP (DS) 5MM (PLAIN)	62061
2210128	ROOLER LOOP (DS) 3MM (GROOVED)	62061
2210129	ROOLER LOOP (DS) 5MM (GROOVED)	62061
2210130	COLLINGS KNIFE (SS) STORZ	62061
2210131	COLLINGS KNIFE (SS) WOLF	62061
2210132	COLLINGS KNIFE (SS) OLYMPUS	62061
2210133	COLLINGS KNIFE (DS) STORZ	62061
2210134	COLLINGS KNIFE (DS) WOLF	62061
2210135	COLLINGS KNIFE (DS) OLYMPUS	62061
2210136	BALL ELECTRODE (DS) 3MM 24CH STORZ	62061
2210137	BALL ELECTRODE (DS) 5MM 24CH STORZ	62061
2210138	BALL ELECTRODE (DS) 3MM 24CH PLAIN STORZ	62061
2210139	BALL ELECTRODE (DS) 5MM 24CH PLAIN STORZ	62061
2210140	BALL ELECTRODE (SS) 3MM 24CH STORZ	62061
2210141	BALL ELECTRODE (SS) 5MM 24CH STORZ	62061
2210142	BALL ELECTRODE (SS) 3MM 24CH PLAIN STORZ	62061
2210143	BALL ELECTRODE (SS) 5MM 24CH PLAIN STORZ	62061
2210144	BALL ELECTRODE (DS) 3MM 27CH STORZ	62061
2210145	BALL ELECTRODE (DS) 5MM 27CH STORZ	62061
2210146	BALL ELECTRODE (DS) 3MM 27CH PLAIN STORZ	62061
2210147	BALL ELECTRODE (DS) 5MM 27CH PLAIN STORZ	62061
2210148	BALL ELECTRODE (SS) 3MM 27CH STORZ	62061
2210149	BALL ELECTRODE (SS) 5MM 27CH STORZ	62061
2210150	BALL ELECTRODE (SS) 3MM 27CH PLAIN STORZ	62061
2210151	BALL ELECTRODE (SS) 5MM 27CH PLAIN STORZ	62061
2210152	BIPOLAR LOOP 24CH DOUBLE STEM BALL	62061
2210153	BIPOLAR LOOP 5MM DOUBLE STEM	62061
2210154	ROLLER LOOP (SS) 5MM (GROOVED)	62061
2210155	CUTTING LOOP (SS) 24CH OLYMPUS	62061

EVACUATOR / Class- IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2009 EN ISO 11607-2:2006
EN ISO 14971: 2012 EN ISO 10993-1:2009/AC:2010 EN 62366:2008
EN ISO 10993-5:2009 EN ISO 10993-12:2012 EN 1618:1997
EN ISO 10993-7:2008/AC:2009 EN ISO 10993-11:2009 EN ISO 11135-1:2007
EN ISO 11135-1:2007 EN ISO 15223-1:2016 EN ISO 11737-1:2006/AC:2009
EN 1041:2008

Reference Number	Product name/Models	GMDN Code
4140003	EVACUATOR	37143
4140004	ELLIK EVACUATOR	37143
BIS	BLADDER IRRIGATION SYSTEM	37143

URETERAL BALLOON DILATORS/ Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2020 EN ISO 11607-2:2020
EN ISO 14971: 2019 EN ISO 10993- 1:2021 EN ISO 10993- 5:2010
ISO 10993- 7:2010 EN ISO 10993-10:2014 EN ISO 10993-12:2013
EN ISO 15223-1:2016 ISO 14644-1: 2015 EN ISO 14644-2:2015
BS EN ISO 11737-1:2018 BS EN 556-1:2009 EN1041+A1:2014
BS EN ISO 11070: 2015 ASTM F1929 - 15 ASTM F 2096 - 11
ASTM D 3078-02(2013) ASTM F 1886 / F1886M - 16 ASTM F 1980-16
ASTM F88 / F88M - 15 TS EN 20696:2018 TS EN 20697:2018
ISO 14644-5: 2006 BS EN ISO 11135:2014 ISO 80369-7:2016
ASTM F1140 / F1140M - 13 NB-MED/2.12/Rec1 MEDDEV. 2.7.1 REV 4
ISO 14644-3: 2019 ISO 14644-4: 2006

Reference Number	Product name/Models	GMDN Code
5100010	TRACKER URETERAL BALLOON DILATOR 5 MMX40MMX75CM	11265
5100011	TRACKER URETERAL BALLOON DILATOR 6 MMX40MMX75CM	11265
5100012	TRACKER URETERAL BALLOON DILATOR 5 MMX60MMX75CM	11265
5100013	TRACKER URETERAL BALLOON DILATOR 6 MMX60MMX75CM	11265
5100014	TRACKER URETERAL BALLOON DILATOR 5 MMX100MMX75CM	11265
5100015	TRACKER URETERAL BALLOON DILATOR 6 MMX100MMX75CM	11265

5100018	TRANCFINDER NEFROSTAMI BALOON DILATOR	11265
5100019	TRACKER URETERAL BALLOON DILATOR	11265

SUPRAPUBIC CATHETERS and SETS / Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017
EN ISO 14971: 2019 EN ISO 10993- 1:2009 EN ISO 10993- 5:2009
ISO 10993- 7:2008 EN ISO 10993-10:2013 EN ISO 10993-12:2012
EN ISO 15223-1:2016 ISO 14644-1: 2015 EN ISO 14644-2:2015
BS EN ISO 11737-1:2018 BS EN 556-1:2001 EN1041:2008+A1:2013
BS EN ISO 11070: 2014 + A1: 2018 ASTM F1929 - 15 ASTM F 2096 - 11
ASTM D 3078-02(2013) ASTM F 1886 / F1886M - 16 ASTM F 1980-16
ASTM F88 / F88M - 15 BS EN 1616:1997 BS EN 1617:1997
BS EN 1618:1997 BS EN ISO 11135:2014 ISO 80369-7:2016
ASTM F1140 / F1140M - 13 NB-MED/2.12/Rec1 MEDDEV. 2.7.1 REV 4

Reference Number	Product name/Models	GMDN Code
4150001	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)8 F 30 CM	34924
4150002	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)10 F 30 CM	34924
4150003	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)12 F 40 CM	34924
4150004	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)14 F 40 CM	34924
4150005	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)16 F 40 CM	34924
4150006	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-SILICON)18 F 40 CM	34924
4150007	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)8 F 30 CM	34924
4150008	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)10 F 30 CM	34924

4150009	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)12 F 40 CM	34924
4150010	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)14 F 40 CM	34924
4150011	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)16 F 40 CM	34924
4150012	SUPRACATH SUPRAPUBIC CATHETER SET (CYSTO-LATEX)18 F 40 CM	34924

AMPLATZ SHEATH AND DILATORS/ Class IIa

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standards below;

EN ISO 13485:2016 EN ISO 11607-1:2017 EN ISO 11607-2:2017

EN ISO 14971: 2019 EN ISO 10993- 1:2009EN ISO 10993- 5:2009

ISO 10993- 7:2008 EN ISO 10993-10:2013 EN ISO 10993-12:2012

EN ISO 15223-1:2016 ISO 14644-1: 2015 EN ISO 14644-2:2015

BS EN ISO 11737-1:2018 BS EN 556-1:2001 EN1041:2008+A1:2013

BS EN ISO 11070: 2014 + A1: 2018 ASTM F1929 - 15 ASTM F 2096 - 11

ASTM D 3078-02(2013) ASTM F 1886 / F1886M - 16 ASTM F 1980-16

ASTM F88 / F88M - 15

Reference Number	Product name/Models	GMDN Code
4130010	UROCROSS® AMPLATZ SHEATH 34 FR.	11265
4130011	UROCROSS® AMPLATZ SHEATH 32 FR.	11265
4130012	UROCROSS® AMPLATZ SHEATH 30 FR.	11265
4130013	UROCROSS® AMPLATZ SHEATH 28 FR.	11265
4130014	UROCROSS® AMPLATZ DILATOR WITH SHEATH 28 FR 30 CM	11265
4130015	UROCROSS® AMPLATZ DILATOR WITH SHEATH 30 FR 30 CM	11265
4130016	UROCROSS® AMPLATZ SHEATH 26 FR.	11265
4130017	UROCROSS® AMPLATZ SHEATH 24 FR.	11265
4130018	UROCROSS® AMPLATZ SHEATH 22 FR.	11265
4130019	UROCROSS® AMPLATZ DILATOR SET 6-30 FR 30 CM	11265
4130020	UROCROSS® AMPLATZ DILATOR SET 6-18 FR 70 CM	11265
INFORSUR® URETERAL ACCESS SHEAT & DILATOR SET (BRAIDED SHAFT CATHETER)		
8121425	INFORSUR® URETERAL ACCESS SHEAT & DILATOR SET 14 FR/25 CM	38821
8121438	INFORSUR® URETERAL ACCESS SHEAT & DILATOR SET 14 FR/38 CM	38821
8121445	INFORSUR® URETERAL ACCESS SHEAT & DILATOR SET 14 FR/45 CM	38821
8121454	INFORSUR® URETERAL ACCESS SHEAT & DILATOR SET 14 FR/54 CM	38821
8121139	INFORSUR® URETERAL ACCESS SHEAT 9,5 X 11,5 FR 39 CM	38821

8121145	INFORSUR®URETERAL ACCESS SHEAT & DILATOR SET 11,5 FR/ 45 CM	38821
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Ureteral Stents - / Class II b

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standarts below;

EN ISO 13485:2016 EN ISO 11607-1:2020 EN ISO 11607-2:2020
 EN ISO 14971: 2019 EN ISO 10993-1:2011 EN ISO 10993-5:2010
 ISO 10993- 7:2010 EN ISO 10993-10:2014 EN ISO 10993-12:2013
 EN ISO 15223-1:2016 ISO 14644-1:2016 ISO 14644-2:2016
 EN ISO 11737-1:2018 EN 1041+A1:2014 EN 556-1:2009
 EN ISO 11070+A1: 2018 TS EN 1618:2000 EN ISO 10993-11:2018
 EN ISO 11135:2014 EN ISO 11140-1:2014 EN ISO 11737-2:2020
 ISO 80369-7:2017 ASTM F1929 – 15 ASTM F 2096 – 11
 ASTM D 3078-02(2013) ASTM F 1886 / F1886M – 16 ASTM F 1980-16
 ASTM F88 / F88M – 15 ASTM D1938 – 14:2014 ASTM D638 – 14:2014
 ASTM D882 – 12:2012 EN ISO 11607-1:2009 ASTM D3078 – 02:2013
 EN 62366-1:2015 ASTM F1140 / F1140M – 13 TS EN ISO 20696:2018
 TS EN ISO 20697:2018 ISO 14644-3:2019 TS EN 17141:2020
 EN ISO 14155:2020 EN ISO 10993-18:2020 EN ISO 10993-4:2020

Reference Number	Product name/Models	GMDN Code
1604708	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 08 CM.	47035
1604710	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 10 CM.	47035
1604712	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 12 CM.	47035
1604714	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 14 CM.	47035
1604716	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 16 CM.	47035
1604718	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 18 CM.	47035
1604720	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 20 CM.	47035
1604722	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 22 CM.	47035
1604724	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 24 CM.	47035
1604726	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 26 CM.	47035
1604728	Lubri-soft Double PigTail Ureteral Stent 4.7 FR. 28 CM.	47035
1606020	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 20 CM.	47035
1606022	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 22 CM.	47035
1606024	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 24 CM.	47035
1606026	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 26 CM.	47035
1606028	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 28 CM.	47035
1606030	Lubri-soft Double PigTail Ureteral Stent 6.0 FR. 30 CM.	47035
1606070	MONO J Ureteral Stent 6.0 FR. 70 CM.	47035
1607020	Lubri-soft Double PigTail Ureteral Stent 7.0 FR. 20 CM.	47035
1607022	Lubri-soft Double PigTail Ureteral Stent 7.0 FR. 22 CM.	47035
1607024	Lubri-soft Double PigTail Ureteral Stent 7.0 FR. 24 CM.	47035
1607026	Lubri-soft Double PigTail Ureteral Stent 7.0 FR. 26 CM.	47035
1607028	Lubri-soft Double PigTail Ureteral Stent 7.0 FR. 28 CM.	47035
1607070	MONO J Ureteral Stent 7.0 FR. 70 CM.	47035
1608020	Lubri-soft Double PigTail Ureteral Stent 8.0 FR. 20 CM.	47035

1608022	Lubri-soft Double PigTail Ureteral Stent 8.0 FR. 22 CM.	47035
1608024	Lubri-soft Double PigTail Ureteral Stent 8.0 FR. 24 CM.	47035
1608026	Lubri-soft Double PigTail Ureteral Stent 8.0 FR. 26 CM.	47035
1608028	Lubri-soft Double PigTail Ureteral Stent 8.0 FR. 28 CM.	47035
1608070	MONO J Ureteral Stent 8.0 FR. 70 CM.	47035
1614708	POLYFLEX Ureteral Stent 4.7 FR. 08 CM.	47035
1614710	POLYFLEX Ureteral Stent 4.7 FR. 10 CM.	47035
1614712	POLYFLEX Ureteral Stent 4.7 FR. 12 CM.	47035
1614714	POLYFLEX Ureteral Stent 4.7 FR. 14 CM.	47035
1614716	POLYFLEX Ureteral Stent 4.7 FR. 16 CM.	47035
1614718	POLYFLEX Ureteral Stent 4.7 FR. 18 CM.	47035
1614720	POLYFLEX Ureteral Stent 4.7 FR. 20 CM.	47035
1614722	POLYFLEX Ureteral Stent 4.7 FR. 22 CM.	47035
161724	POLYFLEX Ureteral Stent 4.7 FR. 24 CM.	47035
1614726	POLYFLEX Ureteral Stent 4.7 FR. 26 CM.	47035
1614728	POLYFLEX Ureteral Stent 4.7 FR. 28 CM.	47035

Drainage Cateters & Sets - Class Ila

which are listed below with their names/models/reference Codes / GMDN code are manufactured in accordance with Harmonised standarts below;

EN ISO 13485:2016 EN ISO 11607-1:2020 EN ISO 11607-2:2020
EN ISO 14971: 2019 EN ISO 10993-1:2021 EN ISO 10993-5:2010
ISO 10993- 7:2010 EN ISO 10993-10:2014 EN ISO 10993-12:2013
EN ISO 15223-1:2016 ISO 14644-1:2016 ISO 14644-2:2016
EN ISO 11737-1:2018 EN 1041+A1:2014 EN 556-1:2009
EN ISO 11070:2015 ISO 14644-4:2006 EN ISO 10993-11:2018
EN ISO 11135:2014 EN ISO 11140-1:2015 ISO 14644-3:2019
ISO 80369-7:2017 ASTM F1929 – 15 ASTM F 2096 – 11
ASTM D 3078-02(2013) ASTM F 1886 / F1886M – 16 ASTM F 1980-16
ASTM F88 / F88M – 15 ASTM D1938 – 14:2014 ASTM D638 – 14:2014
ASTM D882 – 12:2012 EN ISO 11607-1:2009 ASTM D3078 – 02:2013
EN 62366-1:2015 ASTM F1140 / F1140M – 13 TS EN ISO 20696:2018
EN ISO 11737-2:2020 TS EN ISO 20697:2018

Reference Number	Product name/Models	GMDN Code
2200630	FasTrac Drainage Catheter 06.0 FR. 30 CM (P)	10735
2200730	FasTrac Drainage Catheter 07.0 FR. 30 CM (P)	10735

2200830	FasTrac Drainage Catheter 08.0 FR. 30 CM (P)	10735
2200930	FasTrac Drainage Catheter 09.0 FR. 30 CM (P)	10735
2201030	FasTrac Drainage Catheter 10.0 FR. 30 CM (P)	10735
2201230	FasTrac Drainage Catheter 12.0 FR. 30 CM (P)	10735
2201430	FasTrac Drainage Catheter 14.0 FR. 30 CM (P)	10735
2210622	FasTrac Drainage Catheter With Needle 06.0 FR. 22 CM (P)	10735
2210722	FasTrac Drainage Catheter With Needle 07.0 FR. 22 CM (P)	10735
2210822	FasTrac Drainage Catheter With Needle 08.0 FR. 22 CM (P)	10735
2210922	FasTrac Drainage Catheter With Needle 09.0 FR. 22 CM (P)	10735
2211022	FasTrac Drainage Catheter With Needle 10.0 FR. 22 CM (P)	10735
2211222	FasTrac Drainage Catheter With Needle 12.0 FR. 22 CM (P)	10735
2211422	FasTrac Drainage Catheter With Needle 14.0 FR. 22 CM (P)	10735
2220630	FasTrac Drainage Catheter 06.0 FR. 30 CM (P-SU)	10735
2220730	FasTrac Drainage Catheter 07.0 FR. 30 CM (P-SU)	10735
2220830	FasTrac Drainage Catheter 08.0 FR. 30 CM (P-SU)	10735
2220930	FasTrac Drainage Catheter 09.0 FR. 30 CM (P-SU)	10735
2221030	FasTrac Drainage Catheter 10.0 FR. 30 CM (P-SU)	10735
2221230	FasTrac Drainage Catheter 12.0 FR. 30 CM (P-SU)	10735
2221430	FasTrac Drainage Catheter 14.0 FR. 30 CM (P-SU)	10735
2230622	FasTrac Drainage Catheter With Needle 06.0 FR. 22 CM (P-SU)	10735
2230722	FasTrac Drainage Catheter With Needle 07.0 FR. 22 CM (P-SU)	10735
2230822	FasTrac Drainage Catheter With Needle 08.0 FR. 22 CM (P-SU)	10735
2230922	FasTrac Drainage Catheter With Needle 09.0 FR. 22 CM (P-SU)	10735
2231022	FasTrac Drainage Catheter With Needle 10.0 FR. 22 CM (P-SU)	10735
2231222	FasTrac Drainage Catheter With Needle 12.0 FR. 22 CM (P-SU)	10735
2231422	FasTrac Drainage Catheter With Needle 14.0 FR. 22 CM (P-SU)	10735
2240630	FasTrac Drainage Catheter With Needle 06.0 FR. 30 CM (P-SU)	10735
2240730	FasTrac Drainage Catheter With Needle 07.0 FR. 30 CM (P-SU)	10735
2240830	FasTrac Drainage Catheter With Needle 08.0 FR. 30 CM (P-SU)	10735
2240930	FasTrac Drainage Catheter With Needle 09.0 FR. 30 CM (P-SU)	10735
2241030	FasTrac Drainage Catheter With Needle 10.0 FR. 30 CM (P-SU)	10735
2241230	FasTrac Drainage Catheter With Needle 12.0 FR. 30 CM (P-SU)	10735
2241430	FasTrac Drainage Catheter With Needle 14.0 FR. 30 CM (P-SU)	10735
3200630	FasTrac Drainage Catheter SET 06.0 FR. 30 CM (P)	10735
3200730	FasTrac Drainage Catheter SET 07.0 FR. 30 CM (P)	10735
3200830	FasTrac Drainage Catheter SET 08.0 FR. 30 CM (P)	10735

3200930	FasTrac Drainage Catheter SET 09.0 FR. 30 CM (P)	10735
3201030	FasTrac Drainage Catheter SET 10.0 FR. 30 CM (P)	10735
3201230	FasTrac Drainage Catheter SET 12.0 FR. 30 CM (P)	10735
3201430	FasTrac Drainage Catheter SET 14.0 FR. 30 CM (P)	10735
3210622	FasTrac Drainage Catheter SET With Needle 06.0 FR. 22 CM (P)	10735
3210722	FasTrac Drainage Catheter SET With Needle 07.0 FR. 22 CM (P)	10735
3210822	FasTrac Drainage Catheter SET With Needle 08.0 FR. 22 CM (P)	10735
3210922	FasTrac Drainage Catheter SET With Needle 09.0 FR. 22 CM (P)	10735
3211022	FasTrac Drainage Catheter SET With Needle 10.0 FR. 22 CM (P)	10735
3211222	FasTrac Drainage Catheter SET With Needle 12.0 FR. 22 CM (P)	10735
3211422	FasTrac Drainage Catheter SET With Needle 14.0 FR. 22 CM (P)	10735
3220630	FasTrac Drainage Catheter SET 06.0 FR. 30 CM (P-SU)	10735
3220730	FasTrac Drainage Catheter SET 07.0 FR. 30 CM (P-SU)	10735
3220830	FasTrac Drainage Catheter SET 08.0 FR. 30 CM (P-SU)	10735
3220930	FasTrac Drainage Catheter SET 09.0 FR. 30 CM (P-SU)	10735
3221030	FasTrac Drainage Catheter SET 10.0 FR. 30 CM (P-SU)	10735
3221230	FasTrac Drainage Catheter SET 12.0 FR. 30 CM (P-SU)	10735
3221430	FasTrac Drainage Catheter SET 14.0 FR. 30 CM (P-SU)	10735
3230622	FasTrac Drainage Catheter SET With Needle 06.0 FR. 22 CM (P-SU)	10735
3230722	FasTrac Drainage Catheter SET With Needle 07.0 FR. 22 CM (P-SU)	10735
3230822	FasTrac Drainage Catheter SET With Needle 08.0 FR. 22 CM (P-SU)	10735
3230922	FasTrac Drainage Catheter SET With Needle 09.0 FR. 22 CM (P-SU)	10735
3231022	FasTrac Drainage Catheter SET With Needle 10.0 FR. 22 CM (P-SU)	10735
3231222	FasTrac Drainage Catheter SET With Needle 12.0 FR. 22 CM (P-SU)	10735
3231422	FasTrac Drainage Catheter SET With Needle 14.0 FR. 22 CM (P-SU)	10735

And met the requirements of:

Medical Devices Directive 93/42/ EEC Annex II (Excluding Section IV)

Full Quality Assurance System

Notified Body	:	UDEM International Certification Audit Training Centre Industry and Trade Inc. Co.
Notified Body Number	:	2292
Certificate Number	:	M.2016.106.6518
Certificate Exp. Date	:	27.05.2024

HUSEYIN HAMZA- General Manager

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