



DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: CPAP/VPAP Face Mask and Accessories, CPAP/VPAP Nasal Mask and Accessories, Oxygen Therapy and Accessories, Aerosol Therapy, Anesthesia and breathing circuit system and accessories (Single use), Anesthesia and breathing circuit system and accessories (reusable), Resuscitator and Accessories (Single use), Resuscitator and Accessories (Reusable), HME and HMEF, FILTER

Medical Device: As Attachment

Item Code: As Attachment

Classification: Ila

according to Rule 2 in annex IX of directive 93/42/EEC

meets the provision of the directive 93/42/EEC in consideration of the change of the directive 2007/47/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 93/42/EEC annex II, excluding section 4; the manufacturer is fully responsible for the content of declaration of conformity.

Registration No.: 10240-2017-CE-RGC-NA-PS

Notified Body: DNV GL Nemko Presafe A/S (notify body number –2460)

Valid until: November, 12 2023

EU Rep: mdi Europa GmbH

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

The following standards are applied for all devices:

EN 1041:2008, EN ISO 14971:2019, EN ISO 10993-1:2018, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 13485:2016, EN 62366:2008

The following standards are applied to specific products as below:

Medical Group	Standards
CPAP/VPAP Face Mask and Accessories	EN ISO 80369-7:2017, EN ISO 17510:2020, EN ISO 5356-1:2015
CPAP/VPAP Nasal Mask and Accessories	
Oxygen Therapy and Accessories	EN 15986:2011, EN ISO 20789:2019, EN 13544-2 2002+A1 2009, EN 13544-3 2001+A1 2009, EN ISO 5356-1:2015
Aerosol Therapy	EN 15986:2011, EN 13544-1:2007+A1:2009, EN 13544-2 2002+A1 2009, EN ISO 5356-1:2015
Anesthesia and breathing circuit system and accessories (Single use)	EN 15986:2011, EN ISO 80369-7:2017, EN ISO 5367:2014, EN ISO 5362:2006, EN ISO 5356-1:2015
Anesthesia and breathing circuit system and	

accessories (reusable)	
Resuscitator and Accessories (Single use)	EN ISO 10651-4:2009, EN 13544-2:2002+ A1:2009, EN ISO 5356-1:2015, ASTM F2053-20, ASTM F2052, and ASTM F2213
Resuscitator and Accessories (Reusable)	EN ISO 10651-4:2009, EN 13544-2:2002+ A1:2009, EN ISO 5356-1:2015
HME and HMEF	EN ISO 23328-1:2008, EN ISO 23328-2:2009, EN ISO 9360-1:2000, EN ISO 9360-2:2002, EN ISO 5356-1:2015, ASTM F2101
FILTER	EN ISO 23328-1:2008, EN ISO 23328-2:2009, EN ISO 5356-1:2015, ASTM F2101

Taichung, Jan 15, 2021

Place / Date



VP of Sales and Marketing

Attachment of DoC

Medical Group: CPAP/VPAP Face Mask and Accessories

Product Section	Product Type	UMDNS Description	UMDN Code
CPAP Face Mask	10243, 10244, 10245, 10246, 10333, 10334, 10335, 10343, 10344, 10345, 10443, 10444, 10445, 10563, 10564, 10565, 10663, 10664, 10665, 10843, 10844, 10845, 11163, 11164, 11165, 11343, 11344, 11345, 11443, 11444, 11445, 11943, 11944, 11945, 12143, 12144, 12145, 12243, 12244, 12245, 12443, 12444, 12445, 12543, 12544, 12545, 12643, 12644, 12645, 12743, 12744, 12745, 10283, 10284, 10285, 10293, 10295, 10393, 10395, 10397, 10280, 10282, 10263, 10264, 10265, 10266, 10234, 10235, 11339, 11340, 11341, 11342, 13143, 13144, 13145, 13643, 13644, 13645, 14443, 14444, 14445, 13243, 13244, 13245, 11939, 11940, 11941, 11942, 12343, 12344, 12345, 13543, 13544, 13545, 12943, 12944, 12945, 13742, 13743, 13744, 13745, 13830, 13831, 13832, 13843, 13844, 13845	Continuous Positive Airway Pressure Units	11001
VPAP Face Mask	10217, 10214, 10211, 10311, 10312, 10313, 10514, 10515, 10516, 10614, 10615, 10616, 11114, 11115, 11116, 11311, 11312, 11313, 10221, 10223, 10224, 10259, 10207, 10295-01, 10260, 10261, 10262, 10217Y, 10214Y, 10211Y, 10616Y, 12211, 12212, 12213, 12311, 12312, 12313, 10227, 11411, 11412, 11413, 12411, 12412, 12413, 12611, 12612, 12613, 12711, 12712, 12713, 10811, 10812, 10813, 11314, 11315, 11316, 11317, 11314Y, 11315Y, 11316Y, 11317Y, 10212, 10215, 10218, 13511, 13512, 13513, 13521, 13522, 13523, 10624, 10625, 10626, 13801, 13802, 13803, 13811, 13812, 13813, 13814, 13815, 13816	Continuous Positive Airway Pressure Units	11001

Tubing	70243, 70263, 70253, 70273, 71246, 70240, 70241, 70242, 70245, 70246, 70247, 70260, 70261, 70262	Tubing	14238
Connector	70056	Fittings/Adapters	11726
Pressure Meter	10201-001, 10201-002	Manometer, Aneroid	12432

Medical Group: CPAP/VPAP Nasal Mask and Accessories

Product Section	Product Type	UMDNS Description	UMDN Code
CPAP Nasal Mask	10253, 10254, 10255, 10353, 10354, 10355, 10453, 10454, 10455, 10573, 10574, 10575, 10673, 10674, 10675, 10853, 10854, 10855, 11173, 11174, 11175, 11353, 11354, 11355, 11453, 11454, 11455, 12153, 12154, 12155, 12253, 12254, 12255, 12453, 12454, 12455, 12553, 12554, 12555, 12653, 12654, 12655, 12753, 12754, 12755, 12853, 12855, 13253, 13254, 13255, 12953, 12954, 12955, 10273, 10274, 10275, 11349, 11350, 11351, 11352, 12353, 12354, 12355, 13153, 13154, 13155, 14153, 14154, 14155, 14453, 14454, 14455, 14253, 14254, 14255, 14349, 14350, 14351, 14352, 11573, 11574, 11575, 13653, 13654, 13655, 13753, 13754, 13755, 13451, 13452, 13453, 13454	Continuous Positive Airway Pressure Units	11001
CPAP Nasal Pillow Mask	11054, 11254, 13055, 11252, 12000, 12001, 12002, 12003, 12004, 12005, 12009, 12010, 12011, 12012, 12013, 12014, 12015, 12019, 11253, 11255	Continuous Positive Airway Pressure Units	11001
VPAP Nasal Mask	10208, 10205, 10202, 10301, 10302, 10303, 10504, 10505, 10506, 10604, 10605, 10606, 11104, 11105, 11106, 11301, 11302, 11303, 11304, 11305, 11306, 11307, 10207, 10270, 10271, 10272, 10501, 10502, 10503, 10801, 10802, 10803, 11401, 11402, 11403, 12201, 12202, 12203, 12401, 12402, 12403, 12601, 12602, 12603, 12701, 12702, 12703, 13401, 13402, 13403, 13404, 14301, 14302, 14303, 14304	Continuous Positive Airway Pressure Units	11001
Tubing	70243, 70253, 71246, 70240, 70241, 70242, 70245, 70246, 70247, 70260, 70261, 70262, 70263, 70273	Tubes, Other	14238
Pressure Meter	10201-001, 10201-002	Manometer, Aneroid	12432

Medical Group: Oxygen Therapy and Accessories

Product Section	Product Type	UMDNS Description	UMDN Code
Oxygen Mask	30120, 30121, 30122, 30123, 30124, 30125, 30130, 30131, 30132, 30133, 30134, 30135, 30127, 30128, 30581, 30583, 30585, 30591, 30593, 30595, 30144, 30145, 30146, 30147, 30154, 30155, 30156, 30157, 30584, 30594, 30162, 30163, 30164, 30165, 30586, 30596, 30166, 30167, 30180, 30181, 30190, 30191	Masks, Air Oxygen	12448
Nasal Cannula	30202, 30302, 30203, 30303, 30204, 30304, 14952, 14953, 14954, 14955, 14932, 14933, 14934, 14935	Cannulae, Nasal Oxygen	12700
Humidifier Bottle	70529, 70523, 70558	Humidifiers	12047
Oxygen Tubing	30200, 30300, 30245, 30345, 30201, 30301	Tubes, Other	15278
Diluter	30001, 30002, 30003, 30004, 30005, 30006, 30007	Diluters	15133
Adjustable diluter	30020	Diluters	15133
Adaptor	30018, 70083	Fitting/Adapters	11726
Connector	30038, 70181, 70565	Fitting/Adapters	11726

Medical Group: Aerosol Therapy

Product Section	Product Type	UMDNS Description	UMDN Code
Nebulizing Set/Kit	30142, 30143, 30152, 30153, 30183, 30582, 30592, 30148, 30550, 30551, 30158	Nebulizers	12712
Nebulizing Bottle	30500, 30501, 30502, 30503, 30504, 30505, 30506, 30512	Nebulizers	12712
Aerosol Mask	30140, 30141, 30150, 30151, 30580, 30590, 30410, 30411, 30160, 30161, 30182	Masks, Air-Oxygen, Aerosol Admin	12449

Medical Group: Anesthesia and breathing circuit system and accessories (Single use)

Product Section	Product Type	UMDNS Description	UMDN Code
Anesthesia /Breathing Circuit System	70100,70101,70102,70103,70104,70105,70106,70110,70111,70112,70113,70114,70115,70116,70108,70118,70121,70120,70390,70184,70127,70129,70126,70128,70185,70142,70143,70144,70145,70146,70147,70150,70151,70152,70154,70155,70156,70170,70171,70172,70186,70187,70188,70189,70183,70122,70123,70124,70125,70159,70174,70149,70125-300,70125-180	Breathing Circuits, Anesthesia Breathing Circuits Ventilator	Anesthesia Circuit System 10139 Breathing Circuit System 15003
Air cushion mask	20116,20117,20118,20119,20120,20121,20122,20140,20141,20142,20143,20144,20145,20146,20149,20150,20151,20152,20153,20154,20155,20156,20190,20191,20192,20193,20194,20195,20196,20250,20251,20252,20253,20254,20255,20256,20173,20110,20111,20112,20113,20114,20115,20350,20351,20352,20353,20354,20355,20356,20160,20161,20162,20163,20164,20165,20166	Masks, Anesthesia	12453
PVC mask	10143,10144,10145	Masks, Anesthesia	12453
Catheter Mount	70130,70131,70132,70133,70134,70135,70136,70137,70138,70139,70334,70335,70336,70338,70339	Tubes, Rebreathing	14226
Tubing	70202,70204,70205,70208,70209,70229,70228,70309-006	Tubes, Other	15278
CO2 Sampling Line	30300-051	Tubes, Connecting	14188
Rebreathing bag	70509,70510,70511,70512,70505,70506,70507,70508	Breathing Bags	10486
Elbow Connector	70000,70001,70003,70005,70006,70007,70008,70009	Fitting/Adapters	11726
Wye Connector	70010,70011	Fitting/Adapters	11726
Parallel Connector	70013,70062	Fitting/Adapters	11726
Connector	70014,70016,70019,70020,70021,70022,70023,70024,70025,70026,70027,70059,70078,70092,70093,70094,70095,70054,70057,70556,30012,30014,70058,70068,70084,70522,70087	Fitting/Adapters	11726
Connector (one-way-valve)	70018	Valves	14325

Medical Group: Anesthesia and breathing circuit system and accessories (reusable)

Product Section	Product Type	UMDNS Description	UMDN Code
Anesthesia/Breathing Circuit System	70320,70340	Breathing Circuits Ventilator	15003
Accessories: Silicone Mask	10110,10111,10112,10113,10114,10115,10123,10124,10125,10133,10134,10135	Masks, Anesthesia	12453
Catheter Mount	70140,70141,70148,70342,70160	Tubes, Rebreathing	14226
Tubing	70162,70163,70164,70165,70176,70177,70178	Tubes, Other	15278
Rebreathing bag	70501,70502,70503,70504	Breathing Bags	10486
Wye Connector	70416	Fitting/Adapters	11726
Straight Connector	70403,70408	Fitting/Adapters	11726
Elbow connector	70415	Fitting/Adapters	11726

Medical Group: Resuscitator and Accessories (Single use)

Product Section	Product Type	UMDNS Description	UMDN Code
Disposable Manual Resuscitator	60150, 60151, 60152, 60144, 60145, 60146, 60147, 60148, 60149, 60141, 60142, 60143, 60121, 60122, 60123 60111, 60112, 60113, 60101, 60102, 60103, 60107, 60108, 60521, 60522, 60523	Resuscitators Pulmonary, Manual	13367
PEEP Valve (PC)	60013, 60015, 60015-001, 60015-100, 60017, 60019, 60019-100, 60023, 60024	Valves, Positive End-Expiratory Pressure	14337
Pocket Size Resuscitator	30100, 30100-01, 30101, 30101-01, 30102, 30103, 30103-01, 30104	Masks, Mouth-to mask, Resuscitation Training	17550
Pressure meter	60050, 60050-002, 60050-100	Manometer, Aneroid	12432

Medical Group: Resuscitator and Accessories (Reusable)

Product Section	Product Type	UMDNS Description	UMDN Code
Reusable Manual Resuscitator (PC accessories)	60256,60257,60258,60259,60260,60261,60204,60205,60206,60253,60254,60255,60250,60251,60252,60211,60212,60213,60201,60202,60203	Resuscitators Pulmonary, Manual	13367
Reusable Manual Resuscitator (PSF accessories)	60304,60305,60306,60307,60308,60301,60302,60303,60311,60347,60348,60349,60351,60352,60353,60341,60342,60343,60344,60345,60346	Resuscitators Pulmonary, Manual	13367
PEEP Valve (PSF)	60014,60016,60018,60020	Valves, Positive End-Expiratory Pressure	14337

Medical Group: HME and HMEF

Product Section	Product Type	UMDNS Description	UMDN Code
HME & HMEF	70531,70535,70540,70541,70544,70560,70549,70592,70595,70598	Humidifiers, Heat/Moisture Exchange	15645

Medical Group: FILTER

Product Section	Product Type	UMDNS Description	UMDN Code
Filter	70530,70532,70536,70537,70538,70539	Filters, Bacteria	11712