

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: CPAP/VPAP Face 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)

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

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

The following standards are applied for all devices:

EN 1041:2008, EN ISO 14971:2012, EN ISO 10993-1:2009/AC:2010, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 13485:2016, EN 62366:2008, EN 15986:2011

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 17510:2015, EN ISO 5356-1:2015
Oxygen Therapy and Accessories	EN ISO 8185:2009, EN 13544-2 2002+A1 2009, EN 13544-3 2001+A1 2009, EN ISO 5356-1:2015
Aerosol Therapy	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 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
Resuscitator and Accessories (Reusable)	ISO 5356-1:2015

Taichung, Jan 21, 2020

Place / Date



VP of Sales and Marketing

Attachment of DoC

Medical Group: CPAP/VPAP Face Mask and Accessories

Product Section	Product Type
CPAP Face Mask	10295
NIPPV Tubing	70243

Medical Group: Oxygen Therapy and Accessories

Product Section	Product Reference codes
Oxygen Mask	30164,30165
Humidifier Bottle	70523,70558
Oxygen adaptor	70083,EG009-30018,30018

Medical Group: Aerosol Therapy

Product Section	Product Reference codes
Mouth Piece	30011

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

Product Section	Product Reference codes
Anesthesia /Breathing Circuit System	L-70106,70121,70121-1.65, HBSS02-150E1-270,70121-704, 70146WOL,70125,70120-1.65,70125-1.8,HBSS12-IPPB,70151-2.4, 17919-ABSS04-SET1, 17919-ABSS02,17919-ABSS03, 17919-ABSS03-SET1,70142-418B1,70142PVC,L-70121PVC,70143, 70143PVC,70147PVC,70120,70120PVC,70146,70106,70147,70120-1.65
Air cushion mask	20110,20111,20112,20113,20114,20115,20140,20141, 20142,20143,20144,20145,20146,20160,20161,20162, 20163,20164,20165,20166,20173
Catheter Mount	70130,70131,70132,70133,70134,70135,70136-22,70136, 70137-15,70137,70138,70139
Rebreathing bag	70509,70510,70511,70512,70505,70506,70507,70508
Tubing	HS-C70309-004,HS-C70308-004,L-70202,70229,
Connector	EG009-HSV01-6,70019,70020,70012,70027,70057,70065,70084, HBAD01-22M-22F-6
One-way Valve	70017,70018

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

Product Section	Product Reference codes
Anesthesia /Breathing Circuit System	70320,70340
Silicone mask	10110,10111,10112,10113,10114,10115,10123,10124,10125

Product Section	Product Reference codes
Rebreathing bag	70501,70502,70503,70504
Tubing	70163,HS-A70297-001,HS-A70298-001

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

Product Section	Product Reference codes
Connector	70408,70415,70416

Medical Group: Resuscitator and Accessories (Single use)

Product Section	Product Reference codes
Manual Resuscitator	60111H,60112H,60113H,60111H-HS,60141H,60142H,60143H
PEEP Valve	60015,60019
Pocket Size Resuscitator	30101,HBM06-PMB-B/KD,HS-C30107-001,HS-A30100-021,HS-P30101-007,HS-A30100-026,HS-A30100-031,HS-A30100-029,HS-A30100-030,HBM06-PMB-Y,HBM06-PMB-Y/KD,HBM06-PMB-O/KD,HBM06-PMB-R/KD,HBM06-PMB-W/KD,HBM06-PMB-BLK/KD,HBM06-PMB-BLK-T1,HS-C30107-001
Patient Valve	60027,60029

Medical Group: Resuscitator and Accessories (Reusable)

Product Section	Product Reference codes
Manual Resuscitator	60344H,60345H,60346H
PEEP Valve	60016,60020
Patient Valve	60026,60028,HS-A60300-001,60030,HS-C60040,HS-C60041,