Declaration of Conformity to Council Directive 93/42/EEC concerning Medical Devices

Manufacturer:	BMC Medical Co., Ltd. Room 110 Tower A Fengyu Building, No. 115 Fucheng Road, Haidian, Beijing 100036, PEOPLE'S REPUBLIC OF CHINA
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, GERMANY
Product: See appendix	
Conformity assessment Route: Annex ii without chapter 4	
We, BMC Medical Co., Ltd., herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices. All supporting documentation is retained at the premises of the manufacturer. The manufacturer is exclusively responsibility for the DOC.	
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany
Identification Number:	0123
(EC) Certificate(s):	G1 081775 0008 Rev.03
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Place, Date of Issue:	Beijing, 2021-04-14
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Appendix

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
Sleep Apnea Therapy Device and Accessories	RESmart CPAP System	RESmart (also sold as BMC-680C)	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, EN 62304:2006/A1: 2015, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008, ISO 80601-2-70:2015, ISO 80601-2-74:2017, EN ISO 14971:2012, ISO 5356-1:2015, ISO 5367:2014, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
	RESmart Auto CPAP System	RESmart Auto (also sold as BMC-680A)					
	RESmart BPAP System	25 (also sold as BMC-770-25S)					
		25A (also sold as BMC-770-25A)					
		25T (also sold as BMC-770-25T)					
		30T (also sold as BMC-770-30T)					
		20S (also sold as BMC-720-S)					
		20A (also sold as BMC-720-A)					
		20T (also sold as BMC-720-T)					
		BMC-50	12050	Humidifiers, Heated			

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Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
Sleep Apnea Therapy Device and Accessories	Auto CPAP System	M1 Mini	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, ISO 80601-2-70:2015, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, ISO 5356-1:2015, ISO 5367:2014, EN 62304:2006+A1: 2015, ISO 18562-1:2017, ISO 18562-2:2017,ISO 18562-3:2017, ISO 18562-4:2017
Sleep Apnea Therapy Device and Accessories	RESmart GII CPAP System	E-20C-H-O	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, ISO 80601-2-70:2015, EN 62366-1: 2015, EN ISO 15223-1:2016, EN 1041:2008, ISO 80601-2-74:2017, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2012, ISO 5356-1:2015,ISO 5367:2014, EN 62304:2006+A1: 2015, ISO 80601-2-61:2011, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
		E-20CJ-H-O					
	RESmart GII Auto CPAP System	E-20A-H-O					
		E-20AJ-H-O					
	RESmart GII BPAP System	T-20S					
		T-20A					
		T-20T					
		T-25S					
		T-25A					
		T-25T					
		T-30T					
		T-30 T plus					
Respiratory Insufficiency Ventilator and	RESmart GII BPAP System	Y-20T	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 62366-1:2015, EN 60601-1-6:2010+A1:2015, EN 62304:2006/A1:2015,
		Y-25T					

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Accessories		Y-30T				the MDD	EN 60601-1-8:2007/A1:2013, EN ISO 14971:2012, ISO 80601-2-70:2015, ISO 80601-2-79:2018, ISO 80601-2-74:2017, ISO 80601-2-61:2017, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 15223-1:2016, EN 1041:2008, ISO 5356-1:2015, ISO 5367:2014, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
		Y-30AT					
		U-20T					
		U-25T					
		U-30T					
		U-30AT					
	Heated Humidifier	H60	12050	Humidifiers, Heated			
Sleep Apnea Therapy Device and Accessories	CPAP System	G2S C20	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-11:2015, EN 62366-1:2015, EN 60601-1-6:2010+A1:2015, EN 62304:2006/A1:2015, EN 60601-1-8:2007/A1:2013, EN ISO 14971:2012, ISO 80601-2-74:2017, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 15223-1:2016, EN 1041:2008, ISO 5356-1:2015, ISO 5367:2014, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017 **The following apply only to G2S C20 and G2S A20:** ISO 80601-2-70:2015 **The following apply only to G2S B20A, G2S B20A, G2S B20S, G2S B20T, G2S B25A, G2S B25S, G2S B25T, G2S LAB, G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT:** ISO 80601-2-61:2011, ISO 80601-2-79:2018
	Auto CPAP System	G2S A20					
Respiratory Insufficiency Ventilator and Accessories	BPAP System	G2S B20A					
		G2S B20S					
		G2S B20T					
		G2S B25A					
		G2S B25S					
		G2S B25T					
		G2S LAB					
		G2S B25VT					
		G2S B30T					

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		G2S B30VT					
		G2S B30AT					
Sleep Apnea Therapy Device and Accessories	CPAP System	G3 C20	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, ISO 80601-2-61:2011, EN 60601-1-8:2007/A1:2013, EN 1041:2008, EN 62366-1:2015, EN ISO 15223-1:2016, ISO 5367:2014, ISO 80601-2-74:2017, EN ISO 14971:2012, ISO 5356-1:2015, EN 62304:2006+A1: 2015, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017 **The following applies only to G3 C20 and G3 A20:** ISO 80601-2-70:2015 **The following apply only to G3 B20A, G3 B25A, G3 B25S, G3 B25VT, G3 B30SV, G3 B30VT, G3 LAB:** EN 60601-1-8:2007/A1:2013, ISO 80601-2-79:2018
	Auto CPAP System	G3 A20					
Respiratory Insufficiency Ventilator and Accessories	BPAP System	G3 B20A					
		G3 B25A					
		G3 B25S					
		G3 B25VT					
		G3 B30SV					
		G3 B30VT					
		G3 LAB					
Respiratory Insufficiency Ventilator and Accessories	Respiratory Insufficiency Ventilator	R-90S	11001	Continuous Positive Airway Pressure Units	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, ISO 80601-2-61:2011, EN 60601-1-8:2007/A1:2013, EN 1041:2008, ISO 80601-2-79:2018, ISO 80601-2-55:2018, ISO 80601-2-74:2017, EN 62366-1:2015, EN ISO 15223-1:2016, ISO 5367:2014, EN ISO 14971:2012, ISO 5356-1:2015, EN 62304:2006+A1: 2015, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, ISO 18562-1:2017, ISO 18562-2:2017,
		R-80S					
		R-80B					
		R-80C					

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
							ISO 18562-3:2017, ISO 18562-4:2017
Respiratory High-Flow Therapy Device and Accessories	Respiratory High-Flow Therapy Device	H-80M	12050	Humidifiers, Heated	II a	Rule 9 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, EN 60601-1-8:2007/A1:2013, EN 1041:2008, ISO 5367:2014, EN 62366-1:2015, EN ISO 15223-1:2016, EN 62304:2006+A1: 2015, ISO 80601-2-74:2017, EN ISO 14971:2012, ISO 5356-1:2015, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
		H-80A					
		H-80AS					
Masks	iVolve Nasal Mask	BMC-NM	12447	Masks	II a	Rule 2 according to annex IX of the MDD	ISO 17510:2015, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 62366-1:2015, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 5356-1:2014, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
	iVolve N2 Nasal Mask	BMC-NM2					
	N4 Nasal Mask	NM4					
	Nasal Mask	N5					
	Nasal Mask	N5A					
	Nasal Mask	N5B					
	Nasal Mask	N5H					
	Nasal Mask	N5AH					
	Nasal Mask	N5BH					
	Nasal Mask	N5S					

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
	Nasal Mask	N5AS					
	Nasal Mask	N5BS					
	P2 Nasal Pillows Interface	P2					
	Nasal Pillows Interface	P2H					
	Fealite Nasal Pillows System	BMC-PM					
	iVolve Full Face Mask	BMC-FM					
	iVolve F1A Full Face Mask	BMC-FM1A					
	F2 Full Face Mask	BMC-FM2					
	F1B Full Face Mask	F1B					
	F2 NV Full Face Mask	F2 NV1					
	F2 NV Full Face Mask	F2 NV2					
	Full Face Mask	F3					

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
	Full Face Mask	F4					
	Full Face Mask	F5					
	Full Face Mask	F5A					
	Full Face Mask	F5AS					
Tubes	Breathing Tube	L1	15003	Breathing Circuits, Ventilator	II a	Rule 2 according to annex IX of the MDD	EN ISO 13485:2016, ISO 5367:2014, ISO 5356-1:2015, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 62366-1:2015, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
Nasal cannula	Nasal Cannula	NC12S	12700	Cannulae, Nasal Oxygen	II a	Rule 2 according to annex IX of the MDD	EN ISO 13485:2016, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 62366-1:2015, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 18562-1:2017, ISO 18562-2:2017, ISO 18562-3:2017, ISO 18562-4:2017
		NC12M					
		NC12L					
		NC11S					
		NC11M					
		NC11L					
Sleep Apnea Diagnosis Device and Accessories	Sleep Screener	YH-600A Pro	17885	Apnea Monitors, Recording	IIa	Rule 10 According to annex IX of the MDD	EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 62366-1:2015, EN 62304:2006+A1: 2015, EN ISO 15223-1:2016, EN 60601-1-11:2010, ISO 80601-2-61:2011, EN 1041:2008, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2012, IEC 60601-2-47:2012(only apply to H2, H2 Plus, H2 Pro,
	Portable Sleep Diagnostic System	YH-600B Pro					
		H2					
		H2 Plus					

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule	Standards applied
	Polysomnograph	H2 Pro					H2 Elite), IEC 60601-2-26:2012 (only apply to H2 Pro and H2 Elite)
		H2 Elite					