Product List and Application MDD, AIMDD	TÜVRheinland®

Herewith I declare,

- that no application has been lodged with any other notified body for the same products, and/or the same product-related quality system. The products are listed in the attached table;
- to keep the relevant documentation including documents provided by the TÜV Rheinland LGA Products GmbH for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured;
- that all devices in scope must meet the essential requirements set out in Annex I of the directives 93/42/EEC and/or 90/385/EEC;
- to inform TÜV Rheinland LGA Products GmbH without delay if inquiries regarding the products covered by this application are initiated by any European Authorities.
- to inform TÜV Rheinland LGA Products GmbH of any substantial changes to the approved quality system (e. g. changes to procedures which concern the development, the production or the end control), or the product-range covered and/or of any substantial changes to the approved design or the approved product.
- to notify -in addition to the competent authorities- TÜV Rheinland LGA Products GmbH of the following incidents immediately on learning of them:
  - i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
  - ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in paragraph i) to systematic recall of devices of the same type by the manufacturer.

If applicable; in regard to QM systems I additionally declare,

- to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action.
- to submit to the notified body upon request the relevant documentation on the Quality Management System and the necessary documentation on the product information which have to be evaluated (technical documentation);
- to fulfil the obligations imposed by the quality system approved;
- to keep the approved quality system adequate and efficacious;

If I do not have a registered place of business in a Member State (including states having appropriate agreements with the EC), I additionally declare,

- to designate one authorized representative per product who is established in the community;
- to inform the TÜV Rheinland LGA Products GmbH in case of changing the authorized representative(s);
- that the representative must make the relevant product documentation, including the declaration of conformity, available for inspection purposes for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured;
- to sign an agreement with the authorized representative defining clearly interfaces and responsibilities as to comply with the current EC Guidelines on a Medical Devices Vigilance System.

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Name Legal Manufacturer	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.	MDD 93/42/EEC	Annex II.3
Address Legal Manufacturer	South of Floor 7, Block 5 & Floor 6, Block 4, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong P.R. China	Reason for submission of product list	Any other change of existing product list

Code of facilities	Scope of facilities	Name of facility	Address of facility
EAR(1)	European Authorized Representative	Lotus Medical Equipment Limited	26B Cameron Court, Cork Street, Dublin 8, Ireland Tel: +00353-1-6571034 E-mail:peter@lotusme.org
IMF(1)	Internal Manufacturing Facility	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.	South of Floor 7, Block 5 & Floor 6, Block 4, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong P. R. China
EMF(1)	External Manufacturing Facility		

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	R&D(1)	Research & Development	SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.	South of Floor 7, Block 5 & Floor 6, Block 4, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong P. R. China
	OEM(1)	Original Equipment Manufacturer		
	S-ETO(1)	Sterilization by ETO		
	S-Irradiation(1)	Sterilization by Irradiation		
	S-Heat(1)	Sterilization by moist Heat		
	S-Peroxide(1)	Sterilization by Peroxide		

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	S-Liquid(1)	Sterilization by liquid chemical sterilants		
	S-Aseptic(1)	Sterilization by aseptic filling		

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Product List and Application MDD, AIMDD

TÜVRheinland®

Please enter product details below or use a separate controlled list which makes reference to this application (e.g. by refering to the application date)

add a new product	delete the last product	add a copy of last line		table reset						
Product name (as listed on label)	General product group name	Classification Rule including subclause according to Annex IX	Device Class	Allocation of all products into Device Subcategories [NBOG BPG 2009-3]	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only	TD/DD identifier	Choose from above code of facilities	Summary list of related facilities	Code of EU-REP [see above]
Anesthesia Machine model: AX-400	Anesthesia Machine	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Anaesthesia system	37710	No. QR-730-02-07-183		IMF(1);R&D(1);	EAR(1)
Anesthesia Machine model: AX-500	Anesthesia Machine	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Anaesthesia system	37710	No. QR-730-02-07-183		IMF(1);R&D(1);	EAR(1)
Anesthesia Machine model: AX-600	Anesthesia Machine	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Anaesthesia system	37710	No. QR-730-02-07-035		IMF(1);R&D(1);	EAR(1)
Anesthesia Machine model: AX-700	Anesthesia Machine	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Anaesthesia system	37710	No. QR-730-02-07-035		IMF(1);R&D(1);	EAR(1)
Infusion Workstation model: M200	Syringe Pumps	Rule 11 (3.2/7)	IIb	MD 1101 Devi	Infusion Pumps, Syringe	13217	No. QR-730-03-01-009		IMF(1);R&D(1);	EAR(1)
Syringe Pump model: M200A	Syringe Pumps	Rule 11 (3.2/7)	IIb	MD 1101 Devi	Infusion Pumps, Syringe	13217	No. 1201-01-02		IMF(1);R&D(1);	EAR(1)
Infusion Pump model: ME600	Infusion Pumps	Rule 11 (3.2/7)	IIb	MD 1101 Devi	Infusion Pump, general-purpose	13215	No. 1203-059-01		IMF(1);R&D(1);	EAR(1)

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Product name (as listed on label)	General product group name	Classification Rule including subclause according to Annex IX	Device Class	Allocation of all products into Device Subcategories [NBOG BPG 2009-3]	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only	TD/DD identifier	Choose from above code of facilities	Summary list of related facilities	Code of EU-REP [see above]
Neonatal Ventilator model: NV8	Neonatal CPAP Therapy System	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Continuous Positive Airway Pressure Units	11001	No. 0207_080		IMF(1);R&D(1);	EAR(1)
Medical Air/Oxygen Blender model: KL-20	Medical Air/Oxygen Blender	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Oxygen-Air Proportioners	12867	No. 0206-049		IMF(1);R&D(1);	EAR(1)
Neonatal Ventilator model: NV6	Neonatal CPAP Therapy System	Rule 11 (3.2/7)	IIb	MD 1102 Resp	Continuous Positive Airway Pressure Units	11001	No. 0213_048		IMF(1);R&D(1);	EAR(1)
Neonatal Incubator model: B8	Infant Incubator	Rule 9(3.1/1)	IIb	MD 1402 Devi	Incubator, infant, stationary	36025	No. 0691_57		IMF(1);R&D(1);	EAR(1)
Neonatal Incubator model: B6	Infant Incubator	Rule 9(3.1/1)	IIb	MD 1402 Devi	Incubator, infant, stationary	36025	No. 0691_57		IMF(1);R&D(1);	EAR(1)
Neonatal Incubator model: B3	Infant Incubator	Rule 9(3.1/1)	IIb	MD 1402 Devi	Incubator, infant, stationary	36025	No. 0691_57		IMF(1);R&D(1);	EAR(1)
Defibrillator Monitor model: S6	Defibrillator/ Monitor	Rule 10/4 (3.2)	IIb	MD 1302 Mon	Defibrillator/ monitor	11129	No. 0039_44		IMF(1);R&D(1);	EAR(1)
Defibrillator Monitor model: S8	Defibrillator/ Monitor	Rule 10/4 (3.2)	IIb	MD 1302 Mon	Defibrillator/ monitor	11129	No. 0039_44		IMF(1);R&D(1);	EAR(1)

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Product List and Application MDD, AIMDD	TÜVRheinland®

Date	2016-08-09	Location	Shenzhen	Legally binding signature	Mr. CHEN Jian

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