DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9805-2017-CE-KOR-NA-PS Rev. 3.0	PRJC-558665-2017-MSL-KOR	05 July 2022

This is to certify that the quality system of:

CU Medical Systems, Inc.

130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea

For design, production and final product inspection/testing of:

Defibrillator, Defibrillator/monitor with defibrillation electrodes.

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 14 January 2020

Digitally signed by Maxim Victor
Date: 2021.03.03 13:11:29 EET
Reason: MoldSign Signature
Location: Moldova

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replace the Nemko certificate EU1110405 (NB0470) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued after re-certification	05 July 2017
1.0	Model add	02 July 2018
2.0	Pediatric Defibrillation Electrode add (bold font)	17 May 2019
3.0	**Certificate no. 10770-2017-CE-KOR-NA-PS has been merged after the recertification audit completed**	14 January 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Defibrillator	▪ CU-SP1 ▪ CU-SP1 PLUS ▪ NF1201 ▪ NF1200 ▪ NFK200 ▪ **CU-SP1 AUTO**	IIb
Defibrillator/monitor	▪ CU-HD1 ▪ CU-SP2	IIb
Pediatric Defibrillation Electrode	▪ CUA0512P, ▪ CUA0711P, ▪ CUA0809PA ▪ **CUA1102S**	IIb
Defibrillation Electrode	▪ **CUA1007S**	**IIb**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CU Medical Systems, Inc.	130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwondo, Korea

EU Representative
Medical Device Safety Service, GmbH, Schiffgraben 41, 30175 Hannover, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
9807-2017-AQ-KOR-NA-PS Rev. 1.0	**PRJC-558665-2017-MSL-KOR**	**08 November 2004**	**30 November 2021**

This is to certify that the management system of:

CU Medical Systems, Inc.

130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do,
Republic of Korea

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, development, production, sales, distribution and servicing of Defibrillators, ECG monitoring equipment and Patient Monitors.

Place and Date:
Høvik, 04 December 2018

NORWEGIAN
ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

CU Medical Systems, Inc.

No. of Document: DOC-EU-HD(Rev.5)

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer: CU Medical Systems, Inc.

130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea
Tel: +82 (0)33 747 7657
Fax: +82 (0)33 747 7659

EU Authorized Representative: Medical Device Safety Service, GmbH
Schiffgraben 41, 30175 Hannover, Germany

Notified Body: DNV GL Presafe AS CE2460

Certification No. 9805-2017-CE-KOR-NA-PS Rev. 3.0

Type of Product / Model / Classification:

Type of Product	Model No.	Classification
Defibrillator / monitor	**CU-HD1**	IIb, Rule 9 of Annex IX

EU Directive(s): 93/42/EEC concerning medical devices, as amended by 2007/47/EC

Conformity Assessment Route Annex II with the exemption of section 4

Declaration Statement:

We hereby declare that the above mentioned medical device(s) is(are) in conformity with applicable provisions of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices as amended by 2007/47/EC.

Date of Issue: January 14, 2020

Signature: Harkrork, Ra, Chief Executive Officer

EC Certificate Full Quality Assurance System: Certificate CN19/41057

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 22 January 2020 until 05 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 30 April 2015
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/SZX 50010

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Shenzhen Comen Medical Instruments Co., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
Issue 2

Detailed scope

- Electrocardiograph
(Model: CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3, H12, H12A)

- Multi-parameter Patient Monitor for vital physiological parameters
(Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A,STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, Star8000F, OPUS i8, OPUS i10, OPUS i10 Expert, OPUS i12, OPUS i12 pro, OPUS i15)

- Fetal & Maternal Monitor for vital physiological parameters
(Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)

- Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A)

- Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters
(Model: C100, C100B)

- Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system
(Model: STAR8800)

- Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS i3, NC5A)

Vital Signs Monitor for routine check of NIBP, SpO2, ECG, Temperature and Pulse rate
(Model: NC5)

- Specialized Neonatal Monitor for vital physiological parameters
(Model: C60, C66, C68, Datalys 760)

- Infrared Ear thermometer (Model: IRT10, IRT10A)

- Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)

- Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)

-T piece Infant Resuscitation System (model: BQ70, BQ70A)

- Anaesthesia Machine (AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A)
- Infant Radiant Warmer (BQ80, BQ80A)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60124845 0001

Report No.: 17058047 002

Manufacturer:
SHENZHEN COMEN MEDICAL
INSTRUMENTS CO., LTD.
South of Floor 7, Block 5
4th Industrial Area of Nanyou
Nanshan District
Shenzhen
518052 Guangdong
China

Products: Medical Devices

(see attachment for products and site included)

Replaces Approval, Registration No.: HD 60113800 0001

Expiry Date: 2021-11-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-02-02

Date: 2018-02-02

Notified Body

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60124845 0001
Report No.: 17058047 002

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
South of Floor 7, Block 5
4th Industrial Area of Nanyou
Nanshan District
Shenzhen
518052 Guangdong
China

Products:

- Anaesthetic Systems
- Syringe Pumps
- Infusion Workstation
- Infusion Pumps
- Neonatal Ventilators
- Medical Oxygen-air Blenders
- Infant Incubators
- Defibrillator/Monitors

Site included:

No.2 of FIYTA Timepiece Building, Nanhuan Avenue,
Gongming sub-district, Guangming New District,
Shenzhen, 518106, Guangdong, China

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
III
Certifizierungsstelle

S. Liu

Date: 2018-02-02

EC Certificate Full Quality Assurance System: CN15/30546

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

South of Floor 7, Block 5, 4th Industrial Area of Nanyou,
Nanshan District, Shenzhen, 518052, Guangdong, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 06 February 2018 until 05 February 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 February 2021
Issue 7. Certified since 30 April 2015

Certification is based on reports numbered CN/SZX 50010

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Shenzhen Comen Medical Instruments Co., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

- Electrocardiograph (Model: CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3, H12, H12A)
- Multi-parameter Patient Monitor for vital physiological parameters (Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A,STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, Star8000F)
- Fetal & Maternal Monitor for vital physiological parameters (Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)
- Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A)
- Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters (Model: C100, C100B)
- Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system (Model: STAR8800)
- Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B)
- Specialized Neonatal Monitor for vital physiological parameters (Model: C60, C66, C68, Datalys 760)
- Infrared Ear thermometer (Model: IRT10, IRT10A)
- Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)
- Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)
- T-piece Infant Resuscitation System (model: BQ70, BQ70A)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming sub-district, Guangming New District, Shenzhen, 518106, P.R.China

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60113800 0001

Report No.: 17062405 001

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
South of Floor 7, Block 5 &
Floor 6, Block 4, 4th Industrial
Area of Nanyou, Nanshan District,
518052 Shenzhen, Guangdong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60108968 0001

Expiry Date: 2021-11-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-11-16

Date: 2016-10-11

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60113800 0001
Report No.: 17062405 001

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
South of Floor 7, Block 5 &
Floor 6, Block 4, 4th Industrial Area of Nanyou, Nanshan District,
518052 Shenzhen, Guangdong
China

Products:

- Anaesthetic Systems
- Syringe Pumps
- Infusion Workstation
- Infusion Pumps
- Neonatal Ventilators
- Medical Oxygen-air Blenders
- Infant Incubators
- Defibrillator/Monitors

Notified Body

TÜV Rheinland LGA Products GmbH Nürnberg TÜVRheinland Zertifizierungsstelle

S. Liu

Date: 2016-10-11

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.

Product List and Application MDD, AIMDD

TÜVRheinland®

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		

STAMP **SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09**

Product List and Application MDD, AIMDD	TÜVRheinland®

	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		

STAMP **SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09**

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

STAMP

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09

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)

STAMP SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09

Product List and Application MDD, AIMDD

TÜVRheinland®

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)

STAMP SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09

Product List and Application MDD, AIMDD	TÜVRheinland®

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

STAMP

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. / 2016-08-09

EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,LTD
Address:
South of Floor 7, Block 5 & Floor 1 and Floor 6, Block 4, 4th Industrial Area of Nanyou,Nanshan District, Shenzhen, Guangdong 518052, P.R.China

Whose Single Authorized Representative:
Lotus Medical Equipment Limited

Address:
26B Cameron Court, Cork Street, Dublin 8, Ireland

We, the manufacturer, herewith declare that the products

Electrocardiograph
(Model:CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0120

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS United Kingdom Limited
Unit 202B, Worle Parkway, Weston-super-Mare,
BS22 6WA, United Kingdom
Certificate No.: CN15/30546
Issue date: 30 April 2015
Expiry date: 29 April 2020

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shenzhen Comen Medical Instruments Co.,LTD
Address: South of Floor 7, Block 5 & Floor 1 and Floor 6, Block 4, 4th Industrial Area of Nanyou,Nanshan District, Shenzhen, Guangdong 518052, P.R.China

Shen Zhen 2016-6-17
Place, date

Yi Yong
Legally binding signature, Function

Certificate CN15/30544

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

Registered Address:
South of Floor 7, Block 5, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, 518052, Guangdong, P.R. China

Unified Social Credit Code 91440300738806174Y

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The scope of registration appears on page 2 of this certificate.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 30 April 2018 until 29 April 2021 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 4. Certified since 30 April 2015

This is a multi-site certification.
Additional site details are listed on the subsequent page

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

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HC SGS 9001-15 01 0118 M2

Shenzhen Comen Medical Instruments Co., LTD.

ISO 9001:2015

Issue 4.

Detailed scope.

Design, Manufacture and Distribution of Fetal & Maternal Monitor, Multi-parameter Patient Monitor, Specialized Cardiovascular Monitor, Vital Signs Monitor, Specialized Neonatal Monitor, Specialized Fetal& Maternal Monitor, Defibrillator/Monitors, Central Monitoring System Software, Anaesthetic Gas Scavenging System, Infant Incubators, T-piece Infant Resuscitation System, Electrocardiograph, Infrared Ear Thermometer, Anaesthetic Systems, Syringe Pumps, Infusion Workstation, Infusion Pumps, Neonatal Ventilators, Medical Oxygen-air Blenders, Medical Air Compressors, Ceiling Pendant, LED Surgical Light

Further Clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

Additional facilities

Shenzhen Comen Medical Instruments Co., LTD.

Mannufacturing Address:
No. 2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen, 518106, Guangdong, P.R. China

UKAS MANAGEMENT SYSTEMS
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Certificate CN15/30545

The management system of

Shenzhen Comen Medical Instruments Co., LTD.

No. 2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming Sub-district, Guangming New District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 October 2018 until 29 April 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 February 2021
Issue 5. Certified since 30 April 2015

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Shenzhen Comen Medical Instruments Co., LTD.

ISO 13485:2016
EN ISO 13485:2016

Issue 5

Detailed scope

Design, Manufacture and Distribution of
- -Electrocardiograph,
- -Fetal & Maternal Monitor,
- -Multi-parameter Patient Monitor,
- -Specialized Cardiovascular Monitor,
- -Vital Signs Monitor,
- -Specialized Neonatal Monitor,
- -Specialized Fetal/Maternal Monitor,
- -Central Monitoring System Software
- -Infrared Ear thermometer
- -Anaesthetic Gas Scavenging System
- -LED Surgical Light
- -Ceiling Pendant
- -T-piece Infant Resuscitation System
-Anesthesia Machine,
-Infant Radiant Warmer.

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
F10-11& Sect C, F12 of BLDG 1A and F1-5 of BLDG 2 , FIYTA Timepiece Building, Nanhuan Avenue, Matian Subdistrict, Guangming District
518106 Shenzhen Guangdong
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-01-03
Certificate Registration No.:	SX 60144777 0001
An audit was performed. Report No.:	17058047 006
This Certificate is valid until:	2022-11-15

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-01-03

Jason Ran

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60144777 0001
Report No.: 17058047 006

Organization:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
F10-11& Sect C, F12 of BLDG 1A and F1-5 of BLDG 2 , FIYTA Timepiece Building, Nanhuan Avenue, Matian Subdistrict, Guangming District
Shenzhen
518106 Guangdong
P.R. China

Scope:

Products:

- Anaesthetic Systems
- Syringe Pumps
- Infusion Workstation
- Infusion Pumps
- Neonatal Ventilators
- Medical Oxygen-air Blenders
- Medical Air Compressors
- Infant Incubators
- Defibrillator/Monitors

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-01-03

TÜV Rheinland LGA Products Zertifizierungsstelle

Jason Pan