EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer:

Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets,
Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.16 11:59:30 EET
Reason: MoldSign Signature
Location: Moldova

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
Suzhou,
215021 Jiangsu
P.R. China

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

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Tillystraße 2 · 90431 Nürnberg · Germany

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

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

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:	2019-08-07
Certificate Registration No.:	SX 60138020 0001
An audit was performed. Report No.:	15092074 004
This Certificate is valid until:	2022-02-27

Certification Body

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

Date 2019-08-07

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
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. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization:
Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:
Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Humidifier Jar (Bubble Humidifier Jar), Wound Drainage System with and without Trocars, Sterile Urine Meters, Needle Free Connectors, Disposable Nasal Speculums, Disposable Ear Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity Kits and Implements, Mercury-free Clinical Thermometers, Digital Thermometers

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-08-07

Fuxiu Sheng

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization:
Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:
Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Humidifier Jar (Bubble Humidifier Jar), Wound Drainage System with and without Trocars, Sterile Urine Meters, Needle Free Connectors, Disposable Nasal Speculums, Disposable Ear Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity Kits and Implements, Mercury-free Clinical Thermometers, Digital Thermometers

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-08-07

Fuxiu Sheng

EC Certificate

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Manufacturer: Boen Healthcare Co., Ltd.
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Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009

Effective date: 2020-11-18

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TÜV Rheinland LGA Products GmbH

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Declaration of Conformity

Manufacturer: Durico C&T, Inc.
33, Oedap 6-Gil, Sangju-Si
Gyeongsangbuk-Do 37240 Republic of Korea

Phone: +82-2-525-8405
Fax: +82-2-525-7461
E-mail: info@durico.co.kr, http://www.durico.co.kr

European representative: Durico Imaging BVBA
Villastraat 2 C
1830 Machelen, Belgium

Product: Thermal Paper for Video Printer (Super ULSTAR Brand)
Model: ULSTAR-1100HG, ULSTAR-1100HD, ULSTAR-2100HD, ULSTAR-1100HD mibi, ULSTAR-1100HD MATT, ULSTAR-1100S, ULSTAR-1100S mibi, ULSTAR-840HG, ULSTAR-840S

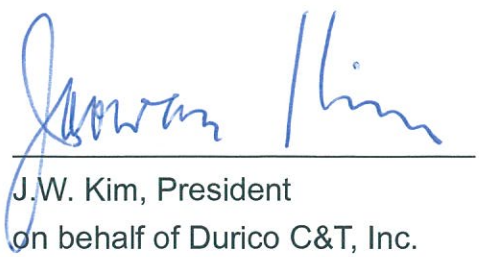
Classification: Class I by the rules of Classification Criteria, Annex IX, MDD 93/42/EEC.

Conformity Assessment Route: Annex VII, MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Place and Date of issue: Korea, May 1, 2019

Signature:



J.W. Kim, President
on behalf of Durico C&T, Inc.

G-CERTI *Certificate*

hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

has been audited and certified as meeting the requirements & Scope of registration

ISO 13485:2016
Medical Devices - Quality Management Systems

Design, Development, Manufacture and Service of Special Paper (Thermal Paper, Ink-jet Paper, Photographic Paper, Mat Sheet)

Certificate No : GK-0233-MD
Valid Period : 05 Jul 2020 ~ 04 Jul 2023
Initial Date : 05 Jul 2014 Issue Date : 01 Jul 2020
Expiry Date : 04 Jul 2023

Signed for and on behalf of GCERTI
President I.K.Choi

G-CERTI SYSTEM SERVICE
MSCB-113

To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F, Surveillance audits shall be conducted at least once a carlendar year, execpt in recetification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.

IAS ACCREDITED
MSCB-113

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Technical Data Sheet
[ULSTAR-1100S, Standard Grade]

Item	Specification		Evaluation Method
Physical Properties	Material	Polypropylene	
	Thickness	85 ± 5 ㎛	TAPPI T-411
	Product Size	Width 110 ± 0.1 mm Length 20 ± 0.1 m	KS B 5203
	Whiteness	88% Min	ASTM E 313
	Maximum Optical Density (Dmax)	1.20 Min	DIN 16536
	Gloss	50% Min	ASTM D 523
	Basis Weight	60 ± 4 g/㎡	TAPPI T-410
Preservation Abilities	Thermal resistance	90% Min	At 50℃, No Color Change during 1 day (Preservability of Max. Optical Density)
	Humidity Resistance	90% Min	At 40℃, 90%RH, 26 hours (Preservability of Max. Optical Density)
	Sunlight Resistance	90% Min	Below sunlight, 28℃, 50%RH, 1day, (Preservability of Max. Optical Density)

1. The data in this sheet represents average and does not constitute a warranty.
2. All the products shall be stored in a dark, cool and dry place below 30℃ / 60% RH.

Certification System

Works and Services, Management Systems

InterSertTest

CERTIFICATION BODY
LIMITED LIABILITY COMPANY
"ISO CONSULTING"

Premises 126, 127, 128, and 129, Block 2, Floor 2, 3, Davydkovskaya Str., Moscow, 121352

CERTIFICATE OF CONFORMITY

Issue 1. QMS is certified since January 2021

№ РОСС RU.C.04ША.СК.1558

Is given to: Research and Production Company "VINAR" Limited Liability Company ("RPC "VINAR", LLC)

TIN 5023001024

Office VIII, Building 7A, 5, Gospitalniy Val, Moscow, 105094

THIS CERTIFICATE CERTIFIES THAT

QUALITY MANAGEMENT SYSTEM AS APPLIED TO DEVELOPMENT, PRODUCTION AND SALES OF THE FOLLOWING PRODUCTS: CHEMICAL AND BIOLOGICAL STERILIZATION, DISINFECTION AND DECONTAMINATION INDICATORS; PROCESS CHALLENGE DEVICES; CHEMICAL INDICATORS FOR DISINFECTING AND STERILIZING SOLUTIONS CONCENTRATION CONTROL; WASH MONITORING AND PRE-CLEANING TESTS; PACKAGING MATERIALS FOR STERILIZATION AND WASHING; "COLD CHAIN" CONTROL INDICATORS; DISPOSABLES FOR STERILIZATION AREAS, OPERATING ROOMS AND CLEAN AREAS; ANTISEPTICS AND DISINFECTANTS

COMPLIES WITH THE REQUIREMENTS OF GOST ISO 13485-2017 (ISO 13485:2016)

By virtue of: *Decision of the Certification Body № 1558 dated 22 January 2021*

THIS CERTIFICATE SHALL BIND THE ORGANIZATION TO MAINTAIN THE STATE OF THE QUALITY MANAGEMENT SYSTEM IN THE WORKABLE CONDITION IN COMPLIANCE WITH THE REQUIREMENTS OF THE ABOVE STANDARD, TO CONFIRM THIS COMPLIANCE BY RESULTS OF THE ANNUAL INSPECTION CHECK-UP IN "ISO CONSULTING" LLC CERTIFICATION BODY WITHIN THE ENTIRE PERIOD OF THE CERTIFICATE DURATION.

Issued: 25 January 2021 ***Expiry date: 25 January 2024***
(If the inspection control is passed)

Terms for the first inspection: Not later than 25 January 2022
Terms for the second inspection: Not later than 25 January 2023

T.V. GRICHANAYA
Deputy Head of the Certification Body

S.T. BUTKINA
Expert

№ 005153

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY
Goodwill Certification System "InterSertTest", Registration №РОСС RU.3570.04ША00
Certification parent body "EuroStandard - certifica" OGRN 1097746081498
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923

Система Сертификации

Продукции, Работ и Услуг, Систем Менеджмента

ИнтерСертТест

ОРГАН ПО СЕРТИФИКАЦИИ
ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ
«ИСО КОНСАЛТИНГ»

121352, г. Москва, ул. Давыдковская, дом 3, этаж 2, блок 2, пом. 126, 127, 128, 129

СЕРТИФИКАТ СООТВЕТСТВИЯ

Выпуск 1. СМК сертифицирована с января 2021 года

№ РОСС RU.С.04ША.СК.1558

Выдан: Обществу с ограниченной ответственностью
Научно-производственная фирма «ВИНАР»
(ООО «НПФ «ВИНАР»)

ИНН 5023001024

105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом. VIII

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ:

Система менеджмента качества применительно к разработке, производству и реализации продукции: химических и биологических индикаторов контроля стерилизации, дезинфекции и обеззараживания; устройств контроля процесса стерилизации; индикаторов экспресс-контроля концентраций рабочих растворов дезинфицирующих и стерилизующих средств; индикаторов контроля эффективности предстерилизационной очистки медицинских инструментов; упаковочных материалов для финишной стерилизации и стирки; индикаторов контроля холодовой цепи; расходных материалов для стерилизационных, операционных, чистых помещений; антисептических и дезинфицирующих средств

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ
ГОСТ ISO 13485-2017 (ISO 13485:2016)

Основание: *Решение Органа по сертификации № 1558 от 22 января 2021 года*

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА В РАБОТОСПОСОБНОМ СОСТОЯНИИ В СООТВЕТСТВИИ С ТРЕБОВАНИЯМИ ВЫШЕУКАЗАННОГО СТАНДАРТА, ПОДТВЕРЖДАТЬ ЭТО СООТВЕТСТВИЕ РЕЗУЛЬТАТАМИ ПРОХОЖДЕНИЯ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ В ОС ООО «ИСО КОНСАЛТИНГ» ВО ВРЕМЯ ВСЕГО СРОКА ДЕЙСТВИЯ СЕРТИФИКАТА.

Дата выдачи: 25.01.2021 ***Срок действия до: 25.01.2024***
(при прохождении инспекционного контроля)

Срок прохождения первого инспекционного контроля: не позднее 25.01.2022
Срок прохождения второго инспекционного контроля: не позднее 25.01.2023

Т.В. ГРИЧАНАЯ **С.Т. БУТКИНА**

Заместитель Руководителя Органа _____ **Эксперт** _____

№ 005153

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
Система добровольной сертификации «ИнтерСертТест», Регистрационный №РОСС RU.3570.04ША00
Головной орган по сертификации «ЕвроСтандарт-сертифика» ОГРН 1097746081498
Адрес: 121170, г. Москва, Кутузовский пр-т, д. 36, стр. 3 тел. (495) 744-2923