



**blue  
sail+**

# GAUKE HEALTHCARE





**GAUKE**<sup>®</sup>

## **ABOUT GAUKE**

JUST SAVE YOU IN TIME

Our Mission:

.To establish the first aid system in China.

.To help more people to survive from disaster.



# PROFESSIONAL MANUFACTURE



Established in 2003  
425 Employees  
**Factory Size: 52,000 m<sup>2</sup>**  
**Annual Revenues: \$50 Million**  
**Main Products:**  
.First Aid Kits  
.Disposable Wound Care  
.PPE  
**Certification:** FDA, MDSAP, CE, ISO13485,  
ISO9001, BSCI  
**Major Market:** EU 85%, USA 15%



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# FIRST AID KIT



GAUKE®

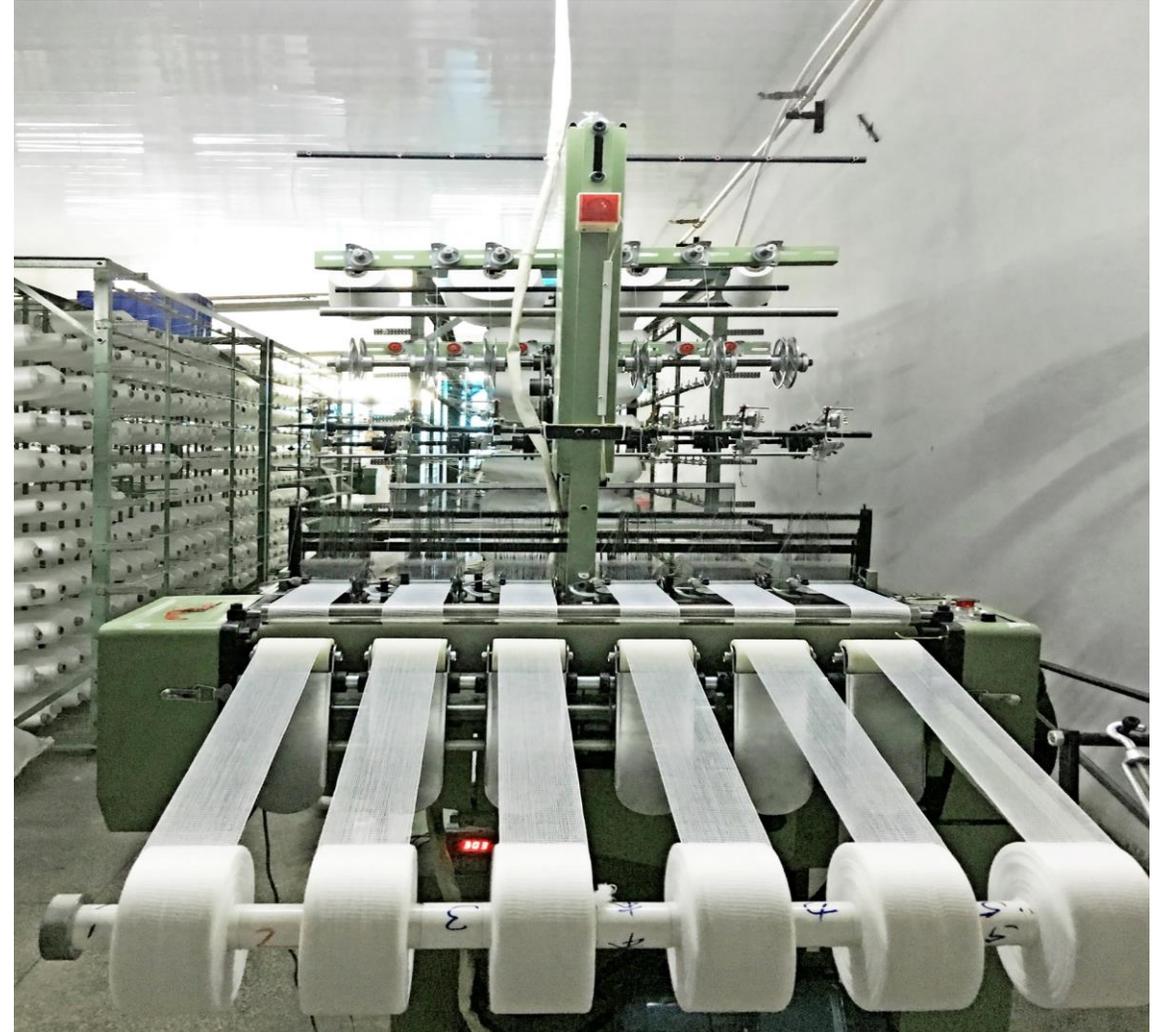




**GAUKE**<sup>®</sup>

**A**

# ELASTIC BANDAGE





**GAUKE**®

**A**

# CLEAN ROOM



**GAUKE Healthcare**



**GAUKE**<sup>®</sup>

**A**

# CLEAN ROOM





**GAUKE**<sup>®</sup>

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# TRIANGULAR BANDAGE & FLOW WRAPPER



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# EMERGENCY BLANKET



GAUKE®



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# WARNING VEST



GAUKE®





GAUKE®

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## WARNING VEST

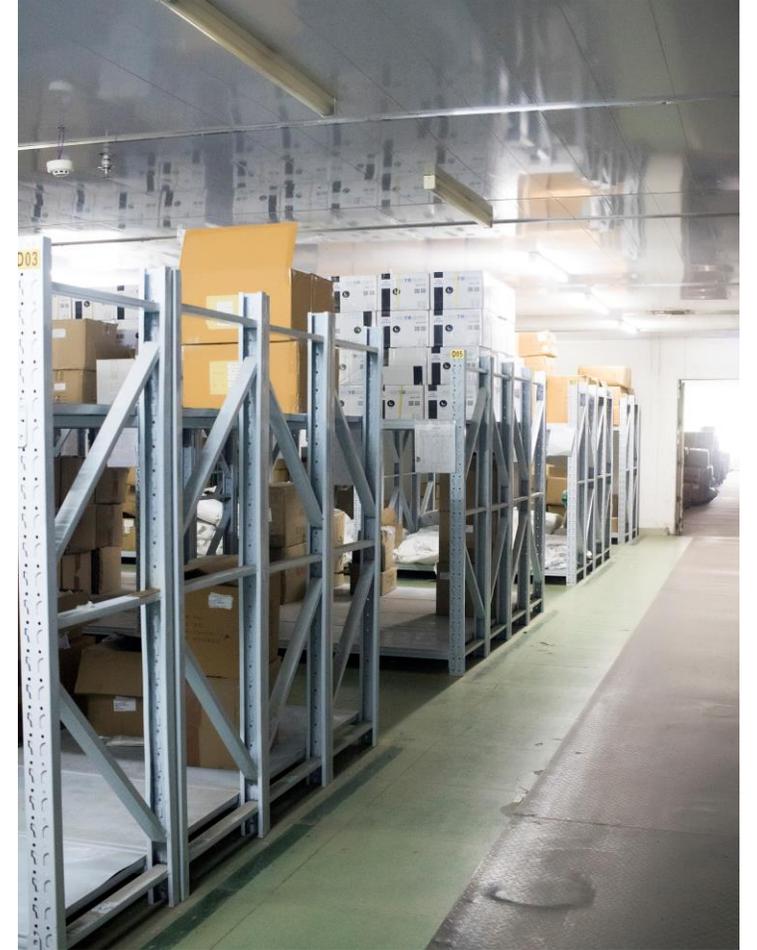


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# WAREHOUSE



GAUKE®





**GAUKE**<sup>®</sup>

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## MAIN TESTING EQUIPMENT





## FDA

**2017**

**CERTIFICATE OF REGISTRATION**

*This certifies that:*  
**GAUKE HEALTHCARE CO., LTD.**  
 Chengnan Industrial Park  
 Tuanfeng County  
 Huanggang Hubei, CHINA 438800

is registered and has listed the following medical device with the U.S. Food and Drug Administration for FY 2017 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration: 3006362781  
 DUNS No.: 54-493-5872  
 Device Classification Name: FIRST AID KIT WITHOUT DRUG  
 Product Code: OHO  
 Regulation Number: 878.4014  
 Registrar Corp  
 144 Research Drive, Hampton, Virginia, 23666, USA  
 Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

*Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

**Registrar Corp**  
 144 Research Drive, Hampton, Virginia, 23666, USA  
 Telephone: +1-757-224-0177 • Fax: +1-757-224-0179  
 info@registrarcorp.com • www.registrarcorp.com

*Raymond K. Statman*  
 Executive Director  
 Registrar Corp  
 Dated: September 4, 2016

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## CE

**EC Certificate**  
 Directive 93/42/EEC Annex V  
 Production Quality Assurance  
 Medical Devices

Registration No.: DD 60108339 0001  
 Report No.: 15091167 001

**Manufacturer:** GAUKE Healthcare Co., Ltd.  
 Chengnan Industrial Park  
 Tuanfeng County  
 HuangGang  
 438800 Hubei  
 China

**Products:** Medical Devices  
 (see attachment for products and additional site included)  
 Replaces Approval, Registration No.: CD 60038109 0001

**Expiry Date:** 2021-03-14

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 IIIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2016-03-15  
**Date:** 2016-03-15

**Notified Body**  
  
 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.

## ISO 13485

**Certificate**

The Certification Body of  
 TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**GAUKE Healthcare Co., Ltd.**  
 Chengnan Industrial Park  
 Tuanfeng County  
 HuangGang  
 438800 Hubei  
 China

has established and applies a quality management system for medical devices for the following scope:  
**(see attachment for scope and additional site included)**

Proof has been furnished that the requirements specified in  
**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

**Effective Date:** 2016-04-02  
**Certificate Registration No.:** SX 80108340 0001  
**An audit was performed. Report No.:** 15091167 001  
**This Certificate is valid until:** 2019-04-01

**Certification Body**  
  
 TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 808-1371 Fax: +49 221 808-3035 e-mail: cert.safety@tuev.com http://www.tuev.com



## MDSAP




By Royal Charter

### Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

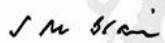
GAUKE Healthcare Co., Ltd  
Chengnan Industrial Park  
TuangFeng County  
Huang Gang  
Hubei  
China

DUNS Number: 54-493-5872

Holds Certificate No: **MDSAP 699696**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Manufacture and Distribution of Medical Gauze Swabs with X-ray Detectable, Medical Lap Sponges with X-ray Detectable, Medical Gauze Balls with X-ray Detectable, Absorbent Cotton Rolls, Absorbent Cotton Balls, Absorbent Cotton Pads, Sterile Single Use Cleansing Products, Cold Packs, Absorbent Gauzes, Sterile Non-woven Sponges/Balls, First Aid Kits, Sterile Bandages, Sterile Dressings, Wound Plaster and Sterile Burn Gel.

  
 Stewart Brain, Head of Compliance & Risk - Medical Devices

For and on behalf of BSI:

Original Registration Date: 2019-07-18    Effective Date: 2019-07-18    Expiry Date: 2022-07-17




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...making excellence a habit.<sup>™</sup>

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory. To be read in conjunction with the scope above or the attached appendix.  
 American Headquarters: BSI Group America Inc., 12550 Wilkshire Drive, Suite 800, Herndon, VA 20170-0007 USA  
 A Member of the BSI Group of Companies.

## BSCI

Producer: **Gauke Healthcare Co., Ltd.**  
 DUNS: 544935872 and Audit No: 68189    Audit Date: 21/10/2016  
 Audit Type: Follow-up Audit



Auditee: **Gauke Healthcare Co., Ltd.**

Audit Date From: **21/10/2016**

Audit Date To: **21/10/2016**

Expiry Date of the Audit: **Please refer to the producer profile in the BSCI platform**

Auditing Company: **TUV Rheinland**

Auditor's Name(s): **Avery Zhu(Lead)**

Auditing Branch (if applicable): **TUV Rheinland China**



**BSCI Audit Summary Report**

This is an extract of the on line Audit Report. The complete report is available in the BSCI Platform. Access [www.bsciplatform.org](http://www.bsciplatform.org), for entitled users only.

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This is an extract of the BSCI Audit Report, which is available in the BSCI Platform. © Foreign Trade Association (FTA), 2013 - The English version is the legally binding One.



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## BSCI

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Summary 🌐

Audit Type	Date	Audit ID	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Follow-up Audit	21/10/2016	68189	C	A	A	A	B	D	A	A	A	A	A	A	A	C
Full Audit	26/10/2016	38540	B	A	A	A	B	D	A	A	A	A	A	A	A	C





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**GAUKE**<sup>®</sup>



## **FIRST AID KITS FOR**

Protecting space

Protecting your world

Just save you in time

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# FIRST AID KIT FOR PROTECTING SPACE



Family



Car



Outdoor



Industry



School



Public

## PUBLIC SPACE

Protecting your world  
Just save you in time



## INDUSTRY SPACE

Protecting your world  
Just save you in time



## SCHOOL SPACE

Protecting your world  
Just save you in time





**GAUKE**<sup>®</sup>

**IMPORTED OTC DRUGS**  
— **SOLUTIONS**

Protecting your world

Just save you in time



**GAUKE**<sup>®</sup>

**A**

# IMPORTED OTC DRUGS



Imported OTC drugs:

.To import OTC drugs from USA under assigned brand.

.To assemble OTC drugs in our duty free warehouse.

.To send complete first aid kits to customers.

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## Cooperation Partner

Providing First aid kit for BLUSAIL, TESLA, Mercedes-Benz, BMW, and any other famous enterprises.





**GAUKE**<sup>®</sup>

Protecting your world  
Just save you in time

**SOCIAL WELFARE FOR LOVE**





GAUKE®

A

# SOCIAL WELFARE



# VISION

**.To establish intergrated Value Chain of R&D,manufacturing,training,and first aid service.**

**.To be the most creative,valuable leading enterprise in China of first aid solution and service.**

# THANKS



**+86-27-8480 3397 -8001**  
**4000161119**

[www.gaukefirstaidkit.com](http://www.gaukefirstaidkit.com)