PRODUCT SPECIFICATION

DIN13164 First Aid Kit-filling

Version: 01 Date:
20.June.2019

Manufacturer:
GAUKE Healthcare Co., Ltd

International Operation:
GAUKE International Trading Co., ltd

Manufacturer: GAUKE Healthcare Co., Ltd.
Manufacturer's Address: GAUKE Industrial Park, Tuanfeng County PO box 438800 Hubei Province, China
Device/s: DIN13164 First aid kit-filling
Description: Used for first aid
Composing:

CODE	Product Name	CE mark	Quantit	Unit	Class	European Representative
F001	Adhesive tape DIN13019-A 5mx2.5cm	CE	1	roll	ClassI	Prolinx GmbH
F002	**Plaster set in foil bag, 14 parts**	**CE**	**1**	**set**	ClassI	Prolinx GmbH
	Adhesive bandages DIN13019-E 10x6		4	pc		
	Finger plaster-elastic 40x65mm		2	pc		
	Finger plaster-elastic 120x20mm		2	pc		
	plaster strips water resistant single packed,19x72mm		2	pc		
	plaster strips water resistant single packed,25x72mm		4	pc		
F031	First aid dressings bandages, Sterile,DIN13151-K,6x8cm	CE0197	1	roll	ClassIs	Prolinx GmbH
F003	First aid dressings bandages, Sterile,DIN13151-M,8x10cm	CE0197	2	roll	ClassIs	Prolinx GmbH
F004	First aid dressings bandages, Sterile,DIN13151-G,10x12cm	CE0197	1	roll	ClassIs	Prolinx GmbH
F005	Sterile Compress(Burn dressings) DIN13152-BR,60x40cm	CE0197	1	pc	ClassIs	Prolinx GmbH
F006	Sterile Compress(Burn dressings) DIN13152-A,60x80cm	CE0197	1	pc	ClassIs	Prolinx GmbH
F007	Conforming Elastic bandages DIN61634 FB6, 6cmx4m	CE	2	roll	ClassI	Prolinx GmbH
F008	Conforming Elastic bandages DIN61634 FB8,8cmx4m	CE	3	roll	ClassI	Prolinx GmbH
F009	First aid blanket,160x210cm	CE	1	pc	ClassI	Prolinx GmbH
F010	Sterile wound compress,10x10cm,2pcs/bag	CE0197	3	bag	ClassIs	Prolinx GmbH
F011	Triangular bandages DIN13168-D,96x96x136cm	CE	2	pc	ClassI	Prolinx GmbH
F012	Scissor DIN58279 A145,145cm	CE	1	pc	ClassI	Prolinx GmbH
F013	Disposable gloves DIN EN 455-1, 4 's L-in zip PP bag	CE	1	bag	ClassI	Prolinx GmbH
F134	Wet wipe for cleaning skin		2	pc	Cosmetics	
F021	Content list		1	pc		
F014	First aid kit manual		1	pc		
	Plastic bag		1	pc		

Declaration of Conformity

GAUKE Healthcare Co., Ltd agrees to develop, implement and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

GAUKE Healthcare Co., Ltd agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

GAUKE Healthcare Co., Ltd confirms that no medicinal products/drugs are incorporated the goods.

GAUKE Healthcare Co., Ltd agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

GAUKE Healthcare Co., Ltd agrees to inform the appointed Notified Body of any planned or unplanned significant changes to the goods, including significant design changes.

GAUKE Healthcare Co., Ltd has appointed as our EU Authorized Representative of: Medical Devices Directive 93/42/EEC
Prolinx GmbH
Brehmstr.56,40239 Duesseldorf, Germany.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Adhesive tape**
umdns code: **10030**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Exanimation Gloves**
umdns code: **11882**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **First Aid Blanket**
umdns code: **10414**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Plaster bandage/Bandages/Triangular bandage**
umdns code: **10274**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Scissor**
umdns code: **13480**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang , 20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Sterile Bandages**
umdns code: **10274**

of class: **Class Is**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII in connection with Annex V**

Registration No.: **DD 60145757 0001**
Exp date: **2024-05-26**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Johnny Sui

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Sterile Dressings**
umdns code: **11315**

of class: **Class Is**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII in connection with Annex V**

Registration No.: **DD 60145757 0001**
Exp date: **2024-05-26**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Johnny Sui

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Sterile Non-woven Sponges / Balls**
umdns code: **13695**

of class: **Class Is**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII in connection with Annex V**

Registration No.: **DD 60145757 0001**
Exp date: **2024-05-26**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Gauke Healthcare Co.,Ltd**

Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China

European Authorized Representative: **Prolinx GmbH**
Brehmstr.56
40239,Duesseldorf
Germany

We declare under our sole responsibility that

the medical device: **Wound Plaster**
umdns code: **10274**

of class: **Class I**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 93/42/EEC Annex VII**

Huanggang,20.June.2019
Place, date

Name and function : Johnny Sui / General manager