



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W016WM

Name of the Device (s) : Disposable medical mask

UDI-DI and Reference No. :

09008163247844

W016

Disposable medical mask EN14683:2019 TYPE I (Non-sterile) 2pcs

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: EN14683:2019 TYPE I (Non-sterile)

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W022WG

Name of the Device (s) : General purpose medical scissors

UDI-DI and Reference No. :

09008163247790

W022

General purpose medical scissors A145-gal

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 58279-A145-gal

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R.China.

Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

Absorbent Non-Woven Compress

Specification:

60×80cm

Intended Use:

These productions are intended to clean skin or wounds, absorb exudates from the body, be used as a mechanical barrier for injury skin.

Basic UDI-DI:

69514547317VF

UDI-DI:

06951454700067

Classification acc. to MDR Ax. VIII:

Class Ia, Rule 4

Applied Standard & Common Specification:

DIN EN 13726-1

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

Notified Body:

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, CE2797

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Matthew Zhang

Name and function :

Matthew Zhang / General manager



Place, date:

Huanggang, 21. 04. 2022

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R.China.

Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

Absorbent Non-Woven Compress

Specification:

10×10-4P

Intended Use:

These productions are intended to clean skin or wounds, absorb exudates from the body, be used as a mechanical barrier for injury skin.

Basic UDI-DI:

69514547317VF

UDI-DI:

06951454700104

Classification acc. to MDR Ax. VIII:

Class Ia, Rule 4

Applied Standard & Common Specification:

DIN EN 13726-1

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

Notified Body:

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, CE2797

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Matthew Zhang

Name and function :

Matthew Zhang / General manager



Place, date:

Huanggang, 21. 04. 2022

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R.China.

Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

First Aid Dressing Bandage

Specification::

8cm × 10cm

Intended Use:

It is intended for non-chronic wound care, or for wound dressings or limbs to provide binding force, to play a binding, fixed role. This product can be loaded into various first aid kits for emergency rescue of the wounded by ambulance personnel at the scene of injury.

Basic UDI-DI:

69514547300UW

UDI-DI:

06951454700036

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

Applied Standard &Common Specification:

EN 14079:2003

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

Notified Body:

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, CE2797

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Matthew Zhang



Name and function :

Matthew Zhang / General manager

Place, date:

Huanggang, 21. 04. 2022

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R.China.

Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

First Aid Dressing Bandage

Specification:

10cm × 12cm

Intended Use:

It is intended for non-chronic wound care, or for wound dressings or limbs to provide binding force, to play a binding, fixed role. This product can be loaded into various first aid kits for emergency rescue of the wounded by ambulance personnel at the scene of injury.

Basic UDI-DI:

69514547300UW

UDI-DI:

06951454700043

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

Applied Standard &Common Specification:

EN 14079:2003

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

Notified Body:

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, CE2797

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Matthew Zhang



Name and function :

Matthew Zhang / General manager

Place, date:

Huanggang, 21. 04. 2022

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R.China.

Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN:

DE-AR-000000087

Product name:

First Aid Dressing Bandage

Specification:

6cm × 8cm

Intended Use:

It is intended for non-chronic wound care, or for wound dressings or limbs to provide binding force, to play a binding, fixed role. This product can be loaded into various first aid kits for emergency rescue of the wounded by ambulance personnel at the scene of injury.

Basic UDI-DI:

69514547300UW

UDI-DI:

06951454702306

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

Applied Standard &Common Specification:

EN 14079:2003

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

Notified Body:

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, CE2797

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Matthew Zhang



Name and function :
Matthew Zhang / General manager

Place, date:
Huanggang, 21. 04. 2022



OFFICIAL STATEMENT

According to Art. 22 of Regulation (EU) 2017/745 on Medical Devices

System/Procedure Pack Producer : Walser Industries China (Hangzhou') Co., Ltd.
Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District,
310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-PR-000040264

Basic UDI-DI : 9001778WALSERFACARYV

Name of the Device (s) : First Aid Kits

UDI-DI and Reference No. :

44258 09008163248261
44276 09008163248278
44281 09008163242368
44282 09008163242375
44283 09008163242504
44286 09008163242726
44287 09008163242733
44288 09008163242399
44289 09008163242405
44290 09008163243181
44291 09008163243198
44292 09008163243679
44293 09008163243686
44294 09008163243730
44295 09008163248285
44296 09008163243891
44297 09008163244263
44299 09008163243983
44300 09008163243976
44301 09008163244805
44302 09008163244799
44303 09008163244782
44304 09008163245529
44305 09008163245536
44306 09008163245987
44307 09008163245970
44308 09008163246250
44309 09008163246403
44311 09001778443113
44312 09001778443120
44313 09001778443137
44255 09008163243099



We declare that:

(a) We have verified the mutual compatibility of the devices in accordance with the manufacturer's instructions and have carried out our activities in accordance with those instructions.

(b) We packaged the system / procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices and other products which have been put together;

(c) the activity of combining devices / other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 05.05.2024



**EU declaration of Conformity
REGULATION (EU) 2017/745**

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W001W8

Name of the Device (s) : Adhesive Tape

UDI-DI and Reference No. :

09008163247851 W001 Adhesive Tape 5mx2,5cm

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 13019-A

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W002WA

Name of the Device (s) : Adhesive Bandages 14pcs

UDI-DI and Reference No. :

09008163247837 W002 Adhesive Bandages14pcs

Risk classification with rule number : Class I, rule 4

Standards and/or specifications: DIN 13019-E10x6, DIN13019-5x4, DIN13019-12x2, DIN13019-7,2x1,9, DIN 13019-7,2x2,5

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



**EU declaration of Conformity
REGULATION (EU) 2017/745**

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778WALSER23P

Name of the Device (s) : First Aid Blanket

UDI-DI and Reference No. :

09008163247813 W009 First Aid blanket 160*210cm

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: gold/silver 160cm*210cm, 12µm

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W010W9

Name of the Device (s) : Elastic Bandage

UDI-DI and Reference No. :

09008163247769

W010

Elastic Bandage FB6 (6*400cm)

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 61634 FB6

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W010W9

Name of the Device (s) : Elastic Bandage

UDI-DI and Reference No. :

09008163247875

W011

Elastic Bandage FB8 (8*400cm)

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 61634 FB8

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W012WD

Name of the Device (s) : Triangular Bandage

UDI-DI and Reference No. :

09008163247868 W012 Triangular Bandage 96*969136cm

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 13168-D

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029



EU declaration of Conformity REGULATION (EU) 2017/745

Manufacturers Name : Walser Industries China (Hangzhou') Co., Ltd.

Manufacturers Address : Room 2009, Diamond Office Building, No. 46 Longshe Road, Shangcheng District, 310008, Hangzhou, Zhejiang, China

Actor ID/SRN : CN-MF-000027017

Authorized Representative Name : Walser GmbH

Authorized Representative Address : Radetzkystrasse 114, 6845 Hohenems, Austria

Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W013WF

Name of the Device (s) : Disposable vinyl examination gloves

UDI-DI and Reference No. :

09008163247806

W013

Disposable vinyl examination gloves 4pcs powder free

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN EN 455

Conformity assessment procedure: Annex II + Annex III

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

Signature :

Name : Marc Hoerburger

Function : Chief Quality and Sustainability Officer

Place and date of issue : Hangzhou, 04.04.2024

Valid until: 04.04.2029