



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

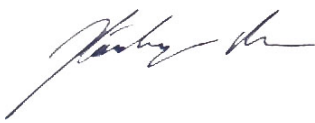
General purpose medical scissors A145-gal

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



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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

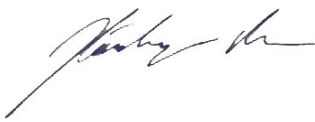
Disposable medical mask EN14683:2019 TYPE I (Non-sterile) 2pcs

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

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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

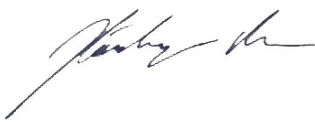
Disposable vinyl examination gloves 4pcs powder free

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN EN 455

Conformity assessment procedure: Annex II + Annex III

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Eudamed Actor ID : AT-AR-000002358

Basic UDI-DI : 9001778W012WD

Name of the Device (s) : Triangular Bandage

UDI-DI and Reference No. :

09008163247868

W012

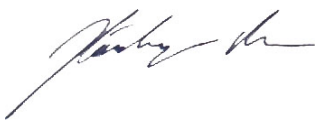
Triangular Bandage 96*969136cm

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 13168-D

Conformity assessment procedure: Annex II + Annex III

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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

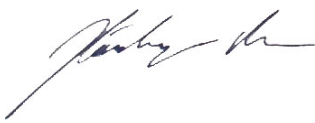
Elastic Bandage FB8 (8*400cm)

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 61634 FB8

Conformity assessment procedure: Annex II + Annex III

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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

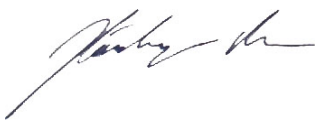
Elastic Bandage FB6 (6*400cm)

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 61634 FB6

Conformity assessment procedure: Annex II + Annex III

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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

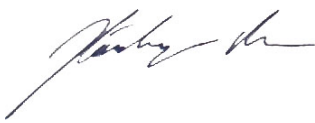
First Aid blanket 160*210cm

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

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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

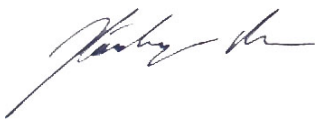
Adhesive Bandages14pcs

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

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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

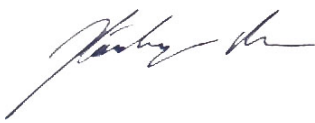
Adhesive Tape 5mx2,5cm

Risk classification with rule number : Class I, rule 1

Standards and/or specifications: DIN 13019-A

Conformity assessment procedure: Annex II + Annex III

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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:

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 Is, 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 Is, Rule 4

**Applied Standard & Common
Specification:**

EN 14079:2003

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

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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 Is, 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

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Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
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 Is, 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:

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Name and function :

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Place, date:

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Trademark:



SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
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 Is, Rule 4

**Applied Standard & Common
Specification:**

DIN EN 13726-1

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

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