

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:



GAUKE[®]

SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Elastic bandage

Product name:

Elastic bandage

Intended Use:

It is intended to provide compression for wound dressing or limbs to play a binding and fixing role.

Basic UDI:

69514547300UW

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

Applied Standard & Common Specification:

DIN 61634

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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

Matthew Zhang

Name and function :
Matthew Zhang / General manager



Place, date:

Huanggang, 21. 04. 2022

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MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

First aid blanket

Product name:

First aid blanket

Intended Use:

It is intended to wrap the limb of the wounded in the
field for heat preservation or heat insulation.

Basic UDI:

69514547306VA

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

DIN13164-2022

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :

Matthew Zhang / General manager

Place, date:

Huanggang, 21. 04. 2022



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Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Scissors

Product name:

Scissors

Intended Use:

Scissors is intended to shear apparatus.

Basic UDI:

69514547307VC

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

DIN 58279

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Cleansing Wipe

Product name:

Cleansing Wipe

Intended Use:

It is intended to clean integrate skin, when the
integrate skin is contaminated by dirty soil, dirty
water or another rubbish.

Basic UDI:

69514547312V5

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

EN 29073: 1992

Conformity assessment procedure:

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CE certificate No.:

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European Representative:

MedPath GmbH

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

SRN:

DE-AR-000000087

Trade name:

Disposable Medical Mask (Non-sterile)

Product name:

Disposable Medical Mask (Non-sterile)

Intended Use:

It is intended to protect the human body from
harmful substances such as germs and viruses. It is
mainly for protection and isolation.

Basic UDI:

69514547309VG

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

EN 14683:2019+AC:2019

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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MedPath GmbH
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80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Adhesive Tapes

Product name:

Adhesive Tapes

Intended Use:

It is used Provide the stickness for fixing dressings and
bandages.

Basic UDI:

69514547308VE

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

DIN 13019

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :

Matthew Zhang / General manager

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Huanggang, 21. 04. 2022



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European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Disposable vinyl Examination gloves

Product name:

Disposable vinyl Examination gloves

Intended Use:

Product can be intended to medical examination to
isolate patients from doctors, patients from patients.

Basic UDI:

69514547316VD

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

**Applied Standard & Common
Specification:**

EN455

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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European Representative:

MedPath GmbH
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80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Triangular bandage

Product name:

Triangular bandage

Intended Use:

Products are intended to provide binding force for
wound dressing or limbs to play a binding and fixing
role.

Basic UDI:

69514547300UW

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**Applied Standard & Common
Specification:**

DIN13168-D

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :
Matthew Zhang / General manager



Place, date:

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Trademark:



GAUKE[®]

SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Adhesive bandage (Non-Sterile)

Product name:

Adhesive bandage (Non-Sterile)

Intended Use:

It is used to block and isolate skin contact with the
outside world, and bandaging nursing.

Basic UDI:

69514547302V2

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

**Applied Standard & Common
Specification:**

DIN 13019

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :

Matthew Zhang / General manager



Place, date:

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European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Absorbent non woven compress

Product name:

Absorbent non woven compress

Intended Use:

It cleans the skin and absorbs the exudates of the
body.

Basic UDI:

69514547317VF

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

**Applied Standard & Common
Specification:**

DIN EN 13726-1

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :
Matthew Zhang / General manager



Place, date:
Huanggang, 21. 04. 2022

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Trademark:



GAUKE[®]

SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

Absorbent Non-Woven Compress

Product name:

Absorbent Non-Woven Compress

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:

69514547317VF

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:

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

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Matthew Zhang

Name and function :
Matthew Zhang / General manager



Place, date:
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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

Trade name:

First Aid Dressing Bandage

Product name:

First Aid Dressing Bandage

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:

69514547300UW

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 :

Johnny Sui / General manager

Place, date:

Huanggang, 21. 04. 2022





INTCO MEDICAL(HK) CO., LTD.

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG
Tel:+86 511 83174088 Fax: +86 511 83174188
Website: www.intco.com.cn

Document Number : CE-DC-001

Version: A/5

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

INTCO Medical (HK) Co., Limited

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN
CHAI, HONG KONG
Tel:+86 511 83174088
Fax: +86 511 83174188

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster,
Germany
Tel: +49-251-32266-0
Fax: +49-251-32266-22

We, the manufacturer, herewith declare that the products

Cold Packs

(HypaCool Instant Cold Pack, Instant Ice Pack Mini, Instant Plus Ice Pack, Instant Ice Pack, INSTANT COLD COMPRESS, HOT & COLD COMPRESS, Instant Soothe COLD pack, Cold Pack, Instant Freeze, Instant cold pack, Instant Cold Compress, cold pad, Instant Cool Pack, instant perineal cold pack, Cool Power Komprese, Sofort Kaelte Komprese, CoolPack Mini, CoolPack Midi, CoolPack Maxi)

Model codes

(CE0406,ICE0506,ICE0507,ICE0508,ICE0509,ICE1069,ICE0609,ICE0505,ICE1125,N14843,N14844,
N14843-KUG,N14843-TED,N14844-KUG,N14844-TED,INSD,KID2,Q2281,F014,F014-1,S454008,VDA,3844,
S454009,VDAA3942,751520-Q,751315-Q,T129525,007800,007909,09135,09136,100196.0,15510,151168,
122864,69710076,710,713,7710,18872,99228,99242,ICE1069,100695,WAL023,ICE0609,SAN-0024, ICE1420,
PER613, ICE1719, CP201,CP202, ICE0408, 51003, 51004, 51005, 51006, 51006, 51007)

UMDNS Code: 10932

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **II a** according to Annex IX, Rule 9 of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to **Annex V and Annex VII** of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 2068388-1

Issue date: 11.09.2020

Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in **Annex V and Annex VII** of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.



INTCO MEDICAL(HK) CO., LTD.

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG

Tel:+86 511 83174088 Fax: +86 511 83174188

Website: www.intco.com.cn

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **INTCO Medical (HK) Co., Limited**

Address: FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG

zhem jiang 2020.9.30
Place, date

Sun Guihua
Legally binding signature, Function

Strážák

9. Declaration of conformity

EC Declaration of Conformity

MANUFACTURER: Nantong Strip Medical Supply Co., Ltd.

Address of the manufacturer: A Building, 182 Yue Long Nan Road, Nantong, Jiangsu, China

TEL: 0086-513-85512391

FAX: 0086-513-85089339

E-MAIL: info.strip@stripmed.com

EU REPRESENTATIVE: Helen Trading Company

ADDRESS: Iztok street, bl.159, 1303 Sofia, Bulgaria

TEL:00359-2-9200456

FAX:00359-2-2921411

E-MAIL: helensf@mail.techno-link.com

Product Name: Alcohol Prep Pad, Cleansing Wipe, Antiseptic Towelette, Antiseptic Spray, Sting Relief Pad, After Shave Wipe, Soap Towelette, Adhesive Tape Remover Pad, Lens Cleansing Towelette, Alcohol Swabsticks, Lemon Glycerine Swabsticks, BZK Prep Pad, Povidone-Iodine Prep Pad; Povidone-Iodine Swabsticks, Alcohol Foam Swabs, Povidone-Iodine Foam Swabs.

Product Classification: I

Quality system we are implementing:

ISO13485:2016 / NS-EN ISO 13485:2016

Certificate No.: 245645-2017-AQ-RGC-NA-PS Rev.1.0

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives (MDD 93/42/EEC), and realize their expected uses. All supporting documentations are retained under the premises of the manufacturer, consequently their authenticity has been guaranteed.

Directives we are following:

European Union Committee Medical Device Directives MDD (93/42/EEC)

Notified body: DNV-GL BUSINESS ASSURANCE (DET NORSKE VERITAS)

General Manager:

Cai Shixiang

Nantong Strip Medical Supply Co., Ltd.

Jan 26, 2019



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Trademark:



GAUKE

SRN:

CN-MF-000013784

European Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

CPR shield

Product name:

CPR shield

Intended use

It is intended to isolate the first-aid person and the injured person in the first aid and prevent the body fluid contact during mouth-to-mouth breathing.

Basic UDI:

69514547304V6

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

Applied Standard & Common Specification:

DIN13154: 2008

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

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Matthew Zhang

Name and function :

Matthew Zhang / General manager

Place, date:

Huanggang, 21. 04. 2022

