DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7,

2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417:2021

Manufacturer

Name: JIANGSU TAIKE MEDICAL TECHNOLOGY CO., LTD

Address: Building 15, No. 18 Qianwan Road, Yangzhou Economic and Technological Development Zone

SRN:

Product Information

Name：MEDICAL DRY FILM

Model：TK-410（14×17）in、TK-410（13×17）in、TK-410（11×14）in、TK-410（10×14）in、TK-410（10×12）in、TK-410（8×10）in、TK-410-A3、TK-410-A4、TK-410-16K、TK-410-B5；

TK-680（14×17）in、TK-680（13×17）in、TK-680（11×14）in、TK-680（10×14）in、TK-680（10×12）in、TK-680（8×10）in、TK-680-A3、TK-680-A4、TK-680-16K、TK-680-B5；

TK-880（14×17）in、TK-880（13×17）in、TK-880（11×14）in、TK-880（10×14）in、TK-880（10×12）in、TK-880（8×10）in、TK-880-A3、TK-880-A4、TK-880-16K、TK-880-B5；

TK-808（14×17）in、TK-808（13×17）in、TK-808（11×14）in、TK-808（10×14）in、TK-808（10×12）in、TK-808（8×10）in、TK-808-A3、TK-808-A4、TK-808-16K、TK-808-B5；

EMDN: Z130101

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z130101-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2024.4.15

Tian Junzhou

Position: GM Place: Jiangsu/China

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021

Manufacturer

Name: JIANGSU TAIKE MEDICAL TECHNOLOGY CO., LTD
Address: Building 15, No. 18 Qianwan Road, Yangzhou Economic and Technological Development Zone
SRN:

Product Information

Name：MEDICAL DRY LASER FILM
Model： TK-JG-A 14in×17in、TK-JG-A 13in×17in、TK-JG-A 14in×14in、TK-JG-A 11in×14in、TK-JG-A 10in×14in、TK-JG-A 10in×12in、TK-JG-A 8in×10in、TK-JG-A A3、TK-JG-A A4、TK-JG-A 16K、TK-JG-A B5;
TK-JG-B 14in×17in、TK-JG-B 13in×17in、TK-JG-B 14in×14in、TK-JG-B 11in×14in、TK-JG-B 10in×14in、TK-JG-B 10in×12in、TK-JG-B 8in×10in、TK-JG-B A3、TK-JG-B A4、TK-JG-B 16K、TK-JG-B B5;
TK-JG-C 14in×17in、TK-JG-C 13in×17in、TK-JG-C 14in×14in、TK-JG-C 11in×14in、TK-JG-C 10in×14in、TK-JG-C 10in×12in、TK-JG-C 8in×10in、TK-JG-C A3、TK-JG-C A4、TK-JG-C 16K、TK-JG-C B5;
EMDN：Z130106
Basic UDI-DI： /
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z130106-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2024.4.15

Tian Jun Zhou

Position: GM Place: Jiangsu/China

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z119099 -03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: **JIANGSU TAIKE MEDICAL TECHNOLOGY CO., LTD**
Address: Building 15, No. 18 Qianwan Road, Yangzhou Economic and Technological Development Zone
SRN:

Product Information

Name: MEDICAL IMAGE PRINTER
Model: TK-3500A、TK-3500F、TK-6600、TK-8800、TK-8808、TK-9900
EMDN: Z119099
Basic UDI-DI: /
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:
Tian Junzhou

Position: GM

Date: 2024.4.15

Place: Jiangsu/China

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z119099-04.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: JIANGSU TAIKE MEDICAL TECHNOLOGY CO., LTD
Address: Building 15, No. 18 Qianwan Road, Yangzhou Economic and Technological Development Zone
SRN:

Product Information

Name：DRY LASER IMAGER
Model：TK-910、TK-910A、TK-910B、TK-990C、TK-3500
EMDN：Z119099
Basic UDI-DI：/
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:
Position: GM

Date: 2024.4.15
Place: Jiangsu/China

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Fascinatio Boulevard 522 (Unit 1.7)
2909 VA Capelle aan den IJssel

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Datum: 3 juni 2024
Betreft: notificatie medische hulpmiddelen klasse I

Ons kenmerk:
CIBG-20241589

Bijlagen
-

Uw aanvraag
30 april 2024

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 30 april 2024 van de notificatie van de medische hulpmiddelen klasse I, die bedrijf Jiangsu Taike Medical Technology Co., Ltd, met Europees gemachtigde SUNGO Europe B.V., als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Dry laser imager
(geen merknaam) (NL-CA002-2024-79206)
Medical dry film
(geen merknaam) (NL-CA002-2024-79203)
Medical dry laser film
(geen merknaam) (NL-CA002-2024-79204)
Medical image printer
(geen merknaam) (NL-CA002-2024-79205)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaande hulpmiddelen te registreren in Eudamed.[3]

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van de bovengenoemde producten slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van de desbetreffende producten als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

Nederlands

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

NOTIS

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Notify Class I medical devices

General data

NOTIS number	20241589
Date of receipt	4/30/2024
Status	Finalised
Date finalised	6/3/2024

Client details

Name	SUNGO Europe B.V.
Contact person concerning this notification	Luo, dhr. R.

Manufacturer details

Authorised representative of manufacturer	Jiangsu Taike Medical Technology Co., Ltd
Address	Building 15, No. 18 Qianwan Road, Yangzhou Economic and Technological Development Zone
Zipcode	225131
City	Jiangsu
Country	CHINA

Products

Brand name *	Group name	Article number(s)	Model(s)	Class	Status
	Medical dry film		TK-410（14×17）in、TK-41...	MDR I	BEV
	Medical dry laser fil...		TK-JG-A 14in×17in、TK-...	MDR I	BEV
	Medical image printer		TK-3500A、TK-3500F、TK-...	MDR I	BEV
	Dry laser imager		TK-910、TK-910A、TK-910...	MDR I	BEV

Documents

Date	File	Title
6/3/2024	20241589-0013.pdf	20241589_1_of_1
6/3/2024	20241589-0014.pdf	MDR Klasse I Bevestiging AR meerdere producten
4/30/2024	20241589-0009.docx	Product information
4/30/2024	20241589-0006.docx	Product information
4/30/2024	20241589-0007.docx	Product information
4/30/2024	20241589-0008.docx	Product information
4/30/2024	20241589-0005.docx	Product information
4/30/2024	20241589-0004.pdf	Declaration of Conformity
4/30/2024	20241589-0001.pdf	Declaration of Conformity
4/30/2024	20241589-0002.pdf	Declaration of Conformity
4/30/2024	20241589-0003.pdf	Declaration of Conformity

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