Traducere din limba engleză

Dosar no.: CE-TCF-001

Declarație de conformitate CE

Cu privire la Directiva privind Dispozitivele Medicale (93/42/CEE)

Inclusiv Directiva 2007/47/CE

Solicitantul

Denumire: XIANTAO JIEMEI PLASTIC PRODUCTS CO., LTD

Adresa: Grupul 3, Localitatea Wanxiangyuan, Biroul Shazui, Orașul Xiantao, Hubei

Reprezentantul CE

Denumire: SUNGO Europe B.V.

Adresa: Olympisch Stadion 24, 1076DE Amsterdam, Țările de Jos

Produsul

Numele: Mască medicală de unică folosință

Tipul: 17,5*9,5 cm (L), 14,5*9 cm (M), 12*7 cm (S)

Clasificare: Clasa I (DDM, Anexa IX), Regula 1 (Toate dispozitivele non-invazive se încadrează în clasa I)

Direcția de evaluare a conformității: Anexa VII

Confirmăm că produsul nostru poate îndeplini cerința Directivei privind Dispozitivele medicale (93/42/CEE) și cerința următoarelor standarde armonizate.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

În numele biroului SUNGO Europe, am confirmat că noi suntem REPREZENTANȚII în UE ai societății care a eliberat prezentul document.

Semnătură indescifrabilă

Semnătură(i) autorizată(e)

Semnătura: *semnătură indescifrabilă*

Data: 30.04.2020

Ștampilă rotundă

Biroul de Traduceri®
Champollion

Tel./fax: 021-327 56 17
office@champollion.ro

Subsemnata **VERDEŞ VIORICA**, traducător autorizat cu nr. **7755/14.01.2015**, certific exactitatea traducerii documentului prezentat din limba engleză în limba română, care a fost vizat de mine.

Traducător autorizat

VERDEŞ VIORICA

File No: CE-TCF-001

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name:Xiantao Jiemei Plastic Products Co., Ltd
Address:Goup 3,Wanxiangyuan Village,Shazui Office,Xiantao City,Hubei

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Medical Mask

Type: 17.5*9.5cm(L), 14.5*9cm(M), 12*7cm(S)

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Signature:

Date: 2020.04.30

EC Declaration of Conformity

Regarding Medical Device Directive 93/42/EEC including

Directive 2007/47/EC

Manufacturer:

Xiantao Jiemei Plastic Products Co., Ltd
Group3, Wanxiangyuan Village, Shazui Office, Xiantao City, Hubei
Tel: +86-728-3277411 Fax: +86-728-3277688

Authorized Representative:

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Tel: +31 (0) 2021 11106

Product Name:	**Disposable medical face mask**
Model Number:	**Earloop 175 × 95mm, 145 × 90mm, 120 × 70mm**

Classification (Medical Device Directive 93/42/EEC, Annex IX): Class I, Rule 1
Conformity Assessment Route: Annex VII

CE

We, the manufacturer, herewith declare that the above-mentioned products meet the provisions of the Directive 93/42/EEC and the following harmonized standards:
EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2013,
EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2019, EN ISO 10993-10:2013,
EN 14683:2019+AC:2019

The above-mentioned declaration of conformity is exclusively under the responsibility of:
Company: Xiantao Jiemei Plastic Products Co., Ltd
Address: Group3, Wanxiangyuan Village, Shazui Office, Xiantao City, Hubei, China

Xiantao 2020/05/20

Place, date

Legally binding signature, Function

Certificate of Registration

This is to certify that the Quality Management System of

Xiantao Jiemei Plastic Products Co., Ltd.

Unified Social Credit Code： 91429004695118864R

Operation Address : Three Group of Wanxiangyuan Village, Shazui Office, Xiantao City, Hubei Province, China

Registered Address : Three Group of Wanxiangyuan Village, Shazui Office, Xiantao City, Hubei Province, China

applicable to

Production and sales of disposable medical non-sterile non-woven protective articles (non-woven masks, non-woven hats, non-woven clothing, non-woven shoe covers)(exported to the United States and the European Union)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number 47217

Date: 05 December 2019

Valid Until: 05 December 2022

EAC Code: 04

UKAS MANAGEMENT SYSTEMS 015