



Medicines & Healthcare products
Regulatory Agency



Our Ref: CA017431

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW

20 March 2020

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Dear Dr Wang

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of **Manufacturers Name:- Tylenol Medical Instruments Co., Ltd.** located at **Manufacturers Address:- 3rd Floor, No.10 Xinhua Road, Sanjiao Town, Zhongshan City, Guangdong, China 528445** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation, certification or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices and Custom Made Active Implantable

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of the following chargeable changes:

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)
- Change of authorised representative

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARAD).



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Thank you for registering the following generic groups of devices:

Class I Devices:

Surgical face mask, single-use

Custom Made Devices:

None

Products Covered By Article 12:

None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

[Malcolm Ridgway](#)

Data Integrity Support Officer

EC declaration of conformity

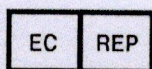


According to COUNCIL DIRECTIVE 93/42/EEC concerning medical devices



Manufacturer: Tylenol Medical Instruments Co., Ltd.

Address : 3rd Floor, No.10, Xinhua Road, Sanjiao Town, Zhongshan City,
Guangdong 528445, China.



WellKang Ltd

Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: Disposable Medical Mask

Product Type: Hanging Ear

Product Classification: Class I

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives MDD93/42/EEC (including 2007/47/EC), and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:

European Union Committee Medical Device Directives MDD93/42/EEC
(including 2007/47/EC).

Standards we are implementing: TN-CE-01-03 List of Harmonized Standards

General Manager:

Company name: Tylenol Medical Instruments Co., Ltd.

Place: ZhongShan City

Date: March 13, 2020

