

# European Authorized Representation Agreement

## European Authorized Representation Agreement

No. 12-1111

**Party A:**

Company Name: **Zhejiang Geyi Medical Instrument Co., Ltd.**  
Company Address: The 5th Floor, NO.4 Building, NO.190 Chutian Road, Xixing Street,  
Binjiang Zone, Hangzhou, Zhejiang 310051, China.  
Tel: +0086-571-8667 6309 Fax: +0086-571-8667 6303

**Party B:**

Company Name: **Lotus Global Co., Ltd.**  
Company Address: 15 Alexandra Road  
London  
NW8 0DP  
United Kingdom

Tel: +0044-20-70961611, +0044-20-75868010 Fax: +0044-20-79006187

Lotus  
Tel: 00  
Fax: 00  
Address  
London

Party A hereby appoints party B as the Authorized Representative within the European Union and party B accepts the appointment to be the Authorized Representative within the single market of the European Union for party A. Both parties enter this agreement as follow:

**Party A**

1. Party A assures to provide the updated technical files of each category products bearing the CE marking to party B.
2. If there are any changes of products, party A shall notify party B at once.
3. Party A shall keep records of serial numbers or production lot numbers for all Products delivered to Party B. Records shall include the following information :
  - a) name and address of the customer,
  - b) product name and specification,
  - c) quantity dispatched,
  - d) date transferred to the customer,
  - e) serial or production lot numbers.

It is agreed that these records shall be available for inspection upon request by party B or by the relevant authorities.

Lotus Global Co., Ltd  
United Kingdom

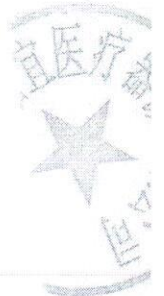
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4. If any serious accident of products occurs within the member states of the European Union, party A shall help party B to investigate the reason in time, and complete the initial report together with party B. Party A shall present the investigation result and final report to party B within the time limit stipulated by EU laws and/or regulations. If the accident of the product occurs outside the member states of the European Union, party A shall notify party B as soon as possible, and make decision whether to report to competent authority or not.
5. Party A shall be responsible for any business dispute such as claim for compensation caused by medical accident after sale, party B may handle the dispute in accordance with the authorization of party A. All the expenses which should be confirmed by party A occurred during the party B's handling of the accident shall be borne by party A.
6. Party A shall be responsible for the content of instruction(user's) manuals, and shall ensure that English language instruction manuals are available to Party B. Party A shall ensure that the required local language instruction manuals are provided to the customers.

Global Co  
144-20-758  
144-20-790  
15 Alexandra  
ton UK, NW

**Party B:**

1. Party B shall be responsible to record all customer and market claims related to the products of Party A and transfer the information to Party A upon receiving of such claims.
2. Party B shall notify Part A about any claims of customers, and change of laws and regulations related to Part A's products bearing CE marking.
3. If any serious accident of products happen within boundary of EU, party B shall notify party A as soon as possible and assist party A to execute vigilance system of medical device products, and also make initial report, investigation result and final report to competent authority of country in which the accidents occur.
4. Party B shall keep technical files of party A's products bearing the CE marking, and take up the responsibility of confidentiality. The technical files shall be kept at least five years after manufacturing the product of last batch. Party B should present the technical files timely to any competent authority that, for vigilance purpose, needs to inspect or audit the technical files.
5. Party B shall keep records of the Products delivered to end-users or distributors so that the traceability of sold products can be performed at any time upon request.





Lotus Global Co., Ltd  
United Kingdom

Appendix A

1. This agreement will be terminated automatically if the CE certification of party A be withdrawn by the notified body during the implementation of the agreement.
2. If party A plans to ship the devices to EU countries and British, party B can support party A to get the devices registered at British according to MHRA and related applicable regulation. This service is not included in this European Authorized Representative Agreement, and party A should inform party B at least 2 months earlier before the shipment and pay the involved registration fee. Currently, party B can only provide support to party A to gain British MHRA registration.
3. Validity term of agreement is for **5 years** after it is signed by European Authorized Representative. (有效期 5 年: 24/SEP/2012-23/SEP/2017)
4. The following countries represent party B's Business Area:  
Europe
5. For the following Product Categories:  
Disposable Circular Staplers II b  
Disposable Linear Cutter Staplers II b  
Disposable Linear Cutter for Endoscope Use II b  
Disposable Linear Staplers II b  
Disposable Circular Stapler for Hemorrhoids II b  
Disposable Trocars II a  
Disposable Suction Irrigation Sets II a

Party A

Zhejiang Geyi Medical Instrument Co., Ltd.

Signature: 郭见清

Date: 2012.9.25

Place: 杭州

Party B

Lotus Global Co., Ltd.

Signature: [Signature]

Date: 24/SEP/2012

Place: London

Lotus Global Co., Ltd  
Tel: 0044-20-75868010  
Fax: 0044-20-79006187  
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