EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Manufacturer:
Name: Hangzhou Yoniner Pharmaceutical Co., Ltd.
Add: Nanyang Economic Development Zone, Xiaoshan, Hangzhou, Zhejiang, China

European Representative:
Company：Lotus NL B.V.
Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31644168999

Product Name: **Medical** Face Mask
Classification and relevant Rule of MDR: I
（MDR MDREU-2017-745 Annex VIII Cleassification rules Rule 4）

Types/Models: **Type I (BFE95%) ;Type II(BFE98%) ;Type IIR(BFE98%)**
The UMDNS code:CIBG-20200693
Product Certification Conformity Assessment Route:
EN 14683：2019 Medical face masks - Requirements and test methods

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promise of the manufacturer.

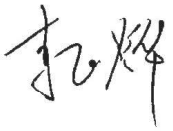
Laws and regulations

Medical Laws and regulations: MDREU-2017-745

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Signature of issue person:
Position: General Manager
Date: 2020.03.13



European Authorized Representation Agreement

No.2424#

Party A:

Company Name: Hangzhou Yoniner Pharmaceutical Co.,Ltd.

Company Address: Nanyang Economic Development Zone,Xiaoshan,Hangzhou,China. 311227

Tel：+0086-571-82172372 Fax：+0086-571-82171268

Party B:

Company Name : **Lotus NL B.V.**

Company Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel：+31644168999 Email：peter@lotusnl.com

Party A hereby appoints party B as the Authorized Representative within the European Union,Turkey and Switzerland, and party B accepts the appointment to be the Authorized Representative within the forsaid area 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.
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.

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 10 years（implantable devices 15 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.

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 ealier before the shipment and pay the involved registration fee(MDD Class I,and all IVDD Products).

3. 3.Validity term of agreement is signed by European Authorized Representative.
（有效期：**25/FEB/2019-15/JUN/2025**）

4. The following countries represent party B's Business Area :
European Union（E.U.）,EEA and Switzerland,Turkey.

5. For the following Product Categories :
Wound bandages(I*), Plasters(I), Wound plasters(I*),
Wound dressings(IIa),
Gauze(IIa) , Sterile gauzes(IIa),
Sterile bandages(I*), Sterile first aid bandages(I*)
Medical tapes(I)(sports tapes,non-woven tapes,paper tapes,elastic tapes,waterproof tapes,PE tapes,silk tapes)
Zinc Oxide plasters(I)
First Aid Kits(I)
Bandages(I), Cohesive bandage(I), First aid kits(I)
Disposal Surgical Masks

Party A	**Party B**
Hangzhou Yoniner Pharmaceutical Co.,Ltd.	**Lotus NL B.V.**
Signature:	Signature:
Date:	Date: **25/MAR/2020**
Place:	Place: **Hague**