



## Qingdao Best Healthcare Products Co.,Ltd.

No.8-5 Guangzhou Road, Pingdu, Qingdao, China.

Tel:+86 532 8435 6677 Fax:+86 532 84356699

### EC DECLARATION OF CONFORMITY to Medical Device Directive 93/42/EEC

**Device Type:** Surgical face mask

**Class :** I

EN14683 Type II Potere filtrante 98%

**Part Numbers:**

⇒ FM-34EE/ET,FM-34PE/PT,FM-33PE/PT,FM-33EE/ET

**Manufacturer:** Qingdao Best Healthcare Products Co.,Ltd.

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Lotus NL B.V.(TEL:+31644168999)  
Koningin Julianaplein 10,Le Verd,2595AA,  
The Hague, Netherlands.

**Best Healthcare Products Co., Ltd. declares that the Medical Device**

- Has been classified as Class I
- Conforms to the Essential Requirements and provisions of the EC Council Directive 93/42/EEC
- Complies with internal certified ISO13485:2003 Quality Management System

**Best Healthcare Products Co., Ltd. agrees to develop, implement and maintain and a formally-recognized Quality Management System to ensure continued adequacy and efficacy.**

**Best Healthcare Products Co., Ltd. agrees to develop, implement and maintain and a documented**

**post-production experience monitoring process, including the notification of reportable events under the Medical Device Vigilance System Guidelines.**

**Best Healthcare Products Co., Ltd. confirms that no medicinal products/drugs are incorporated in any device covered by the present Declaration of Conformity.**

**Best Healthcare Products Co., Ltd. confirms that it is solely responsible for disclosed information.**

Qingdao 08.06.2019

Best Healthcare Products Co.,Ltd. Representative



**Sam Shao, General manager**