



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: Dental face mask/surgical face mask
Class : I

Part Numbers:

⇒ FMS33PE,FMS33EE,FMS34PE,FMS34EE

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 EVERCLEAR

- 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 ISO13485:2016 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 Co.,Ltd. confirms that it is solely responsible for disclosed information.

Qingdao 03.23,2020

Best Healthcare Products Co.,Ltd. Representative



Sam Shao, General manager