
Declaration of Conformity

Manufacturer: RFX + CARE Manufacturing Co., Ltd.

Address: 7 Lan jiang Road, Yuecheng District, Shaoxing, P. R. China

EC-Representative: RFX+CARE International A/S.

Address: Bakkegaardsvej 408, 3050 Humlebaek, Denmark

Product Name: Bee Plaster

Specifications: 38mmx38mm

UMDNS Code: 13708

MD code: MD 0101

Classification (MDD, Annex IX): Class I, rule 1

Conformity Assessment Route: Annex VII

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

RFX + CARE Manufacturing Co., Ltd. is exclusively responsible for the declaration of conformity.

Medical Device Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body: TÜV SÜD Product Service GmbH

Ridlerstrasse 65, 80339 München, Germany

NB Identification number: 0123

(QMS) Certificate(s): Q5 067759 0027 Rev.01

Expire date of the Certificate: 2022-10-31

Start of CE Marking: 2018-12

Place, Date of Issue: **Shaoxing, 2020-02-21**

General Manager (Signature): Benjamin

Date: 2020-02-28

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