

Declaration of Conformity

Manufacturer: RFX + CARE Manufacturing Co., Ltd.

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

EC-Representative: RFX+Care International A/S

Address: Bakkegaardsvej 408, 3050 Humlebaek, Denmark

Item number: FA200-12470516 / 700904 / 700921 / FA200-12470511 /
FA200-12470509 / FA200-12470508 / FA200-12470507 / FA200-12470505 /
FA200-12470503 / FA200-12470500

Product Name: Mykit Tick Set

UMDNS Code: 11723

Specification:

Item No.	Name	Specification	Classification
45125	Plaster	72x25mm	I, Rule 4
45124	Plaster	56x19mm	I, Rule 4
45118	PE plaster, carton	56x19mm	I, Rule 4
47229	PE plaster, carton	45x19mm	I, Rule 4
45120	PE plaster, carton	72x25mm	I, Rule 4
45280	Skin cleansing swab	3x3cm	I sterile, Rule 1
45203	Refreshing wipe	/	Cosmetic
45726	Tick remover	S, M	I, Rule 1
45179B	Tick remover	Blue	I, Rule 1

Classification of Product: Class I sterile, Rule 1

Conformity Assessment Route: Annex V.3

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

(EC) Certificate(s): G2S 067759 0029 Rev.00

Expire date of the Certificate: 2023-11-05

Start of CE Marking: 2008-11-06

Place, Date of Issue: **Shaoxing, 2023-06-15**

General Manager (Signature): 

Date: 2023-06-15

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