

## 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

Product Name: 700380 Eye Wash refill

UMDNS Code: 11655

Specification:

Item No.	Name	Specification	Classification
700380	Eye wash	250 ml	I sterile, Rule 5

Classification of Product: Class I sterile, Rule 5

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, 2023-03-20**

General Manager (Signature):  \_\_\_\_\_

Date: 2023-03-20

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