



Hangzhou Bever Medical Devices Co., Ltd.

Add: Building 2, No. 1-1, Houmuqiao, Yongle Village, Cangqian Street, Yuhang District, Hangzhou, China
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EU Declaration of Conformity

Manufacturer:

Hangzhou Bever Medical Devices Co., Ltd.
Building 2, No. 1-1, Houmuqiao, Yongle Village, Cangqian Street, Yuhang District, Hangzhou, China

Declare that the Class I Sterile BEVER Nasopharyngeal Airways listed in the attached list are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and are subject to the procedures set out in Annex V of the Directive 93/42/EEC.

Intended Purpose: Nasopharyngeal airway is used as an adjunct by inserting through one nostril to maintain an open airway on patients that are unable to protect their own airway due to a depressed level of consciousness.

Sterilization Method: EO

Applied Standards:

No	Standards	Description
1	ISO 14971:2019	Medical devices - Application of risk management to medical devices
2	ISO 13485:2016	Medical devices - Quality management systems -- Requirements for regulatory purposes
3	ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
4	ISO 10993-1 :2018	Biological evaluation of medical devices-Part 1:Evaluation and testing
5	ISO 10993-5 :2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
6	ISO 10993-7:2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
7	ISO 10993-10 :2021	Biological evaluation of medical devices-Part 10: Tests for skin sensitization
8	ISO 10993-23:2021	Biological evaluation of medical devices-Part 23:Tests for irritation

EU Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Notified Body:

TÜV SÜD Product Service GmbH, Zertifizierungstelle, Ridlerstrasse 65, 80339 München, Germany/ identification no.0123

Revision/Date	Declaration No.
01/24 May, 2023	DOC 393/NA

-Certificate Registration No.: G2S 069211 0017 Rev. 01 (valid until 2024-05-26)

Product List:

Nasopharyngeal Airways

See attached product list for individual stock series.

Bever is exclusively responsible for the Declaration of Conformity.

24 - May - 2023
DATE

Allyson Zhou
AUTHORIZED SIGNATURE
Allyson Zhou/Hangzhou

Management Representative
TITLE

Revision/Date	Declaration No.
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Product List Attachment

Product Name	Product code	SKU	UMDNS Code
Nasopharyngeal Airway	110001~110013	Flange style, beveled-tip	10057
Nasopharyngeal Airway	110029~110041	Trumpet style, beveled-tip	10057

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