

Ningbo Luke Medical Devices Co., Ltd.	Document No.: LK-TF-30
	Version: 5
CE Technica l F i l e o f Na so pharyngea l A irway	Issue date: 2024-06-27

01 Declaration of Conformity

Manufacturer :

Name : Ningbo Luke Medical Devices Co.,Ltd.
Add : Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China European Representative :
Name :Shanghai International Holding Corp.GmbH(Europe)
Add : Eiffestrasse 80 ,20537 Hamburg , Germany

Production Name: Nasopharyngeal Airway
Production Sizes:2.5mm/3.0mm/ 3.5mm/4.0mm/4.5mm/5.0mm/5.5mm/6.0mm/6.5mm/7.0mm/7.5mm/8.0mm/8.5mm/9.0mm/9.5mm

Tel:+49-40-2513175 Fax:+49-40-255726
UMDNS Code :10057

Classification (MDD, Annex IX) : Is
Classification and relevant Rule of MDD 93/42/EEC: Annex IX, Rule 5
Conformity Assessment Route : Annex V.3 ofMDD 93/42/EEC

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. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General Applicable Directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device(MDD 93/42/EEC).
Amended by DIRECTIVE 2007/47/EC of 5 September 2007.
Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification Number : CE0123

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(EC) Certificate(s) :GCQ 086250 0024 Rev. 00) (CL 086250 0025 Rev. 01)

Expire Date of the Certificate : 2028-12-31

Start ofCE Marking : 2016-11-04

Place, Date of Issue :Yuyao

Signature: 

Name : Cheng Liu

Position : **General Manager**

Ningbo Luke Medical Devices Co., Ltd.	Document No.: LK-TF-30
	Version: 4
CE Technical File of Nasopharyngeal Airway	Issue date: 2024-05-20