1. EC Declaration of Conformity

Manufacturer:

NINGBO FORMED MEDICAL TECHNOLOGY CO.,LTD
Yang Village, Huangtan Town, Ninghai County, 315608, Ningbo, Zhejiang, China

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Laryngeal Mask
UMDNS-Code:10053;

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **IIa** according to Rule 5 of Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0123

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH
Ridlerstr.65·80339 MÜNCHEN Germany
Certificate No.: G2 12 02 79078 002
Valid from: 2012-02-24
Valid until: 2017-02-23

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: NINGBO FORMED MEDICAL TECHNOLOGY CO., LTD
Address: Yang Village, Huangtan Town, Ninghai County, 315608, Ningbo, Zhejiang, China

Ningbo, 2012-01-10
Place, date

Legally binding signature, Function

2.5 Contraindication

- Use the product during the validity period
- The product is forbidden for use if the individual package is damaged
- Greater than 14 to 16 weeks pregnant
- Patients with multiple or massive injury
- Massive thoracic injury
- Massive maxillofacial trauma
- Patients at risk of aspiration

NOTE: Not all contraindications are absolute (except &).

2.6 Classification

The Laryngeal Mask is non-active and invasive devices with respect to body orifices. The devices are intended for transient use. According to MDD 93/42/EEC **Annex IX Rule 5**, the Laryngeal Mask belongs to class **IIa** medical devices.

2.7 Conformity Assessment Procedure

According to MDD 93/42/EEC, the company has applied for the certification of the CE marked products through the conformity assessment procedure Annex V.3.

2.8 List of applicable regulations and standards:

1	MDD 93/42/EEC under consideration of council directive 2007/47/EC	Medical Devices Directive
2	EN ISO 13485:2003+AC:2007	Medical devices-Quality management systems-Requirements for regulatory purposes
3	EN 556-1:2001+AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
4	EN 980:2008	Graphical symbols for use in the labeling of medical devices
5	EN 1041:2008	Information supplied by the manufacturer of medical devices
6	EN ISO 5356-1:2004	Anaesthetic and respiratory equipment – Conical connectors-Part 1: Cones and sockets
7	EN ISO 10993-1:2009	Biological evaluation of the medical devices-Part 1: Guidance on selection of tests
8	EN ISO 10993-5:2009	Biological evaluation of the medical devices-Part 5: Tests for cytotoxicity: in vitro methods
9	EN ISO 10993-7:2008+AC:2009	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals
10	EN ISO 10993-10:2010	Biological evaluation of the medical devices-Part 10: Tests for irritation and sensitization

11	EN ISO 10993-12:2009	Biological evaluation of medical devices-Part 12: Sample preparation and reference materials
12	EN ISO 11135-1:2007	Medical devices- Validation and routine control of ethylene oxide sterilization
13	EN ISO 11138-2:2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
14	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems
15	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes
16	EN ISO 11737-1:2006	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
17	EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
18	EN ISO 14155-1:2009	Clinical investigation of medical devices for human subjects - Part 1: General requirements
19	EN ISO 14155-2:2009	Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans
20	EN ISO 14644-1:1999	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
21	EN ISO 14644-2:2000	Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
22	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
23	EN ISO 14698-2:2003+AC:2006	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
24	EN ISO 14971:2009	Medical devices-Application of risk management to medical devices
25	MEDDEV 2.12-1 rev 6:2009	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM