EU Declaration of Conformity

MANUFACTURER
(name and address): Haiyan Kangyuan Medical Instrument Co.,Ltd.
Songpodong Road Shendang Town,Haiyan, Zhejiang 314311, China.

SRN: CN-MF-000001532

AUTHORIZED REPRESENTATIVE
(name and address): Eunitor GmbH
Kennedydamm 540476 Düsseldorf Germany

PRODUCTS:

Product Name	Basic UDI-DI	Description	Classification
Endotracheal Tubes for Single Use	6948097004GQCGDH	This product is suitable for oral/nasal insertion into the trachea, and is used when the patient needs to breathe during clinical anesthesia and emergency resuscitation.	Class IIa; Rule 5
Sterile Suction Catheters for Single Use	6948097006XTGMF	This product is used for clinical sputum aspiration.	Class IIa; Rule 5
Oxygen Masks for Single Use	6948097008SYMZLV	This product with oxygen system connection, provide oxygen for clinical patients to use.	Class IIa; Rule 2
Nasal Oxygen Cannulas for Single Use	6948097009BYGK5	This product with oxygen system connection, provide oxygen for clinical patients to use.	Class IIa; Rule 5
Guedel Airways for Single Use	6948097010KYQ6	This product is suitable for clinical patients with airway obstruction, maintain airway patency.	Class IIa; Rule 5
Laryngeal Mask Airways	6948097011HZQ4	The product is suitable for use in patients who need general anesthesia and emergency resuscitation, or to establish short-term non deterministic artificial airway for patients who need breathing.	Class IIa; Rule 5
Anesthesia Masks for Single Use	6948097014MZMZJR	This product can be clinically used to anesthesia breathing.	Class IIa; Rule 2
Breathing Filters for Single Use	6948097015GLQJS	This product is associated with anesthesia breathing equipment and lung function instrument, used to filter particles in the air above 0.5μm.	Class IIa; Rule 2
Breathing Circuits for Single Use	6948097016HXHLGP	The product should be used together with the anesthesia machine, ventilator, tidal device and nebulizer for clinic patients to establish a respiratory connection channel.	Class IIa; Rule 2

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED: Applied standards are listed in the General Safety and Performance Requirements Checklist

NOTIFIED BODY: DEKRA Certification B.V.
Meander 1051 /6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem, The Netherlands
Notified body number: **0344**

EU CERTIFICATE: 6122159CE01

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE: N/A

Place, Date of issue: Haiyan, February 01, 2023

SIGNATURE:

Yaling Xu
Regulatory Affairs Supervisor
For and on behalf of Haiyan Kangyuan Medical Instrument Co.,Ltd