

EC Declaration of Conformity

For the following products :

Product Name : Respiratory Therapy Devices With Accessories

Model / Designation : NCS-100~NCS-900 series Respiratory Therapy Devices and Its Accessories (Manual Resuscitator, Anesthesia Masks, Anesthesia and Ventilator Breathing Circuits and HME Filters, Oxygen Masks, Nasal Cannulas), NCS-712 Laryngeal Mask Airways and series, NCS-713 Endotracheal Tubes and series, NCS-714 Laryngoscope Blades and series.

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning :

MEDICAL DEVICE DIRECTIVE (93/42/EEC As Amended by 2007/47/EC).

with the compliance the essential requirement – Annex I and the conformity assessment procedure described in Article 11.2.b and **Annex V (Module D1)** to be certified by DNV GL Nemko Presafe AS (notify body number – 2460)

For the evaluation regarding the **Class IIa** product safety aspects, the following **harmonized standards** are applied:

ISO 13485:2016 / EN 980 : 2008 / EN ISO 10993-1 : 2009 / EN ISO 14971 : 2012 / EN13544-2:2002+A1:2009

The following European Authorized Representative is stated to the declaration:

Company Name : Arena Electronic GmbH

Company Address : AirCom Park D1 & D2 , Halskester , 22-26 , 40880 Ratingen ,
Germany.

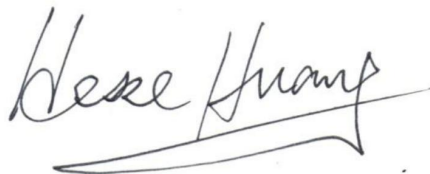
The following person is responsible for the compliance of declaration:

Manufacturer : Non-Change Enterprise Co., Ltd

Place : Facility I: 9F.-11, No.20, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 24159, Taiwan

Facility II: 6F.-11, No.12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 24159, Taiwan

President



2017-07-10

(Name / Position)

(Legal Signature)

(Date)