



## DECLARATION OF CONFORMITY

**MANUFACTURER:** TENACORE HOLDINGS INC.

**ADDRESS:** 1525 E. EDINGER AVE., SANTA ANA, CA-92705

**EUROPEAN REPRESENTATIVE:** ROBERT BANKS  
MILTON KEYNES BUSINESS CENTRE,  
FOXHUNTER DRIVE, MILTON KEYNES, MK14 6GD  
U.K  
TEL: 01908 766143

**PRODUCT(S):** TENACORE HIGH-LOW FLOW OXYGEN BLENDER, TENACORE LOW  
FLOW OXYGEN BLENDER

**CLASSIFICATION:** CLASS II A, RULE 3

**CONFORMITY ASSESSMENT ROUTE:** ANNEX II

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED UNDER 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTAION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED:** ISO 13485: 2003; ISO 14971: 2012; EN 15223-1:2012; EN 1041:2008; ISO 11195:1995

**NOTIFIED BODY:** LNE / G-MED NORTH AMERICA, INC.  
10605 CONCORD STREET, SUITE 205, KENSINGTON, MD 20895  
IDENTIFICATION NUMBER: 0459

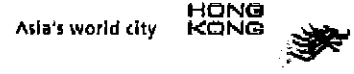
**PLACE, DATE OF ISSUE:** SANTA ANA, CALIFORNIA  
06/20/2013

**SIGNATURE:**

**DIRECTOR OF QUALITY AND REGULATORY AFFAIRS**



**Department of Health**  
The Government of the Hong Kong Special Administrative Region



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Medical Devl

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## Search Database

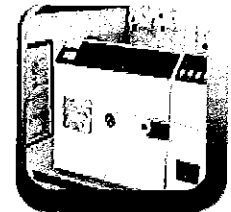
Search Database » **GMDN System**

### • The Global Medical Device Nomenclature (GMDN)

Code : 44485  
 Term : Air-oxygen blender  
 Definition :  
 Synonym code : 36327  
 Template Specifier : nil  
 Category 1 : Anaesthetic and respiratory devices

A category that includes devices and accessory devices used for supplying, conditioning, monitoring, dispensing and delivering respiratory, medical and anaesthetic gases and vapours to provide and/or controlling respiration and/or anaesthesia. Examples of devices in this category are: anaesthetic workstations, respiratory circuits, ventilators.

Whether for product identification? : Not for Product Identification



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