CE 2460

DECLARATION OF CONFORMITY

Oxytek Medical technology Co.,Ltd
10-2, Guang Long Industrial Park, South 1st Rd, Chencun Town, Shunde District, Foshan City, Guang Dong Province, China
Tel: 0755-23733851

Declares under our sole responsibility that the product:

Product Name: Lovego Oxygen Concentrator

Product Model: LG102 LG102P
LG103 LG502
LG1002

Device Classification and Rule: Class IIa, Rule 9

Global Medical Device Nomenclature Code (GMDN): 12873 Oxygen Concentrator

To which this Declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC Medical Devices Directive, as amended up to and inclusive of Council Directive 2007/47/EC.

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 5 of the Medical Device Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.

Notified Body: DNV GL NEMKO PRESAFE AS

Authorized EU Representative: CGI Business Trading and Consulting e.K
Hans-Bethe-Str.1, 60438 Frankfurt am Main, Germany

Supplementary Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the harmonized standards listed below.

Harmonized Standard:	Title:
EN ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests

Signature:
Printed Name: Kai Lee
Title: Senior Quality Assurance Manager

Date: November 24, 2018
Place of Issue: Guangdong