

Declaration of Conformity

Manufacturer: **Well Lead Medical Co., Ltd.**
C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou,
People Republic of China

European Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, GERMANY

Product Name: Oxygen Tubing

Size: 7ft, 10ft, 14ft, 25ft, 50ft (incl. PVC(DEHP) and PVC(DEHP-free))

UMDNS Code: 14188

Classification (MDD, Annex IX): **Ila, Rule 2**

Conformity Assessment Route: **Annex II excluding (4)**

We herewith declare in our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

DIRECTIVES

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339,
München, Germany

Identification number: CE0123

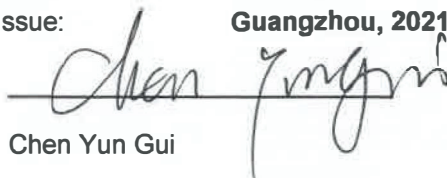
(EC) Certificate(s): **G1 038814 0087 Rev. 01**

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2021-02-19**

Place, Date of Issue: **Guangzhou, 2021-02-20**

Signature:



Name: Chen Yun Gui

Position: **Management Representative**



Annex

Article Number	Product Description
820310	Oxygen Tubing 213cm
820320	Oxygen Tubing 426cm
820330	Oxygen Tubing 750cm
820340	Oxygen Tubing 1521cm