

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 Catheter

Size: 8Fr, 10Fr, 12Fr, 14Fr

UMDNS Code: 12702

Classification (MDD, Annex IX): **Ila, Rule 5**

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. 00**

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

Start of CE Marking: **2008**

Place, Date of Issue: **Guangzhou, 2020-03-31**

Signature: _____

Name:

Chen Yun Gui

Position:

Management Representative



Size	REF Code	Description
10Fr	UM192010	UNO O2CATH FOAM MLE CH10/40CM100X600INT
12Fr	UM192012	UNO O2CATH FOAM MLE CH12/40CM100X600INT
14Fr	UM192014	UNO O2CATH FOAM MLE CH14/40CM100X600INT
10Fr	UM192110	UNO O2CATH FOAM FNL CH10/40CM100X600INT
10Fr	PP192010	PHRMPLT O2CATH FOAM MLE CH10/40CM100X600INT
12Fr	PP192012	PHRMPLT O2CATH FOAM MLE CH12/40CM100X600INT
14Fr	PP192014	PHRMPLT O2CATH FOAM MLE CH14/40CM100X600INT