wellead 维力

Document Nr.: WL-DOC-009/A

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:	Intubating Stylet
Model or Size:	Type: n type (with sleeve) Size: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr Type: n type (without sleeve) Size: 6Fr, 10Fr, 14Fr Type: e type (with sleeve) Size: 6Fr, 10Fr, 14Fr"
UMDNS Code:	14084

Classification (MDD, Annex IX): **IIa, 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 0086 Rev. 01**
Expire date of the Certificate:	**2024-05- 26**
Start of CE Marking:	**2005**
Place, Date of Issue:	**Guangzhou, 2021-02-20**
Signature:	
Name:	Chen Yun Gui
Position:	**Management Representative**

WELL LEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

Add: C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Tel: +86 20 84758878
Web: http://www.welllead.com.cn/

Annex

Article Number	Product Description
844025	Intubating Stylet, Size 6FR
844040	Intubating Stylet, Size 10FR
844050	Intubating Stylet, Size 14FR

Add: C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Tel: +86 20 84758878
Web: http://www.welllead.com.cn/