wellead 维力

Document Nr.: WL-MDR-DOC-009-01-17/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People's Republic of China
SRN:	CN-MF-000006728
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrase 80, 20537 Hamburg, GERMANY
SRN:	DE-AR-000000001
Product Name:	Intubating Stylet
Intended Purpose:	Intubating Stylet is intended to facilitating the insertion, or exchange of Tracheal Tubes.
Type/ Size/ Catalogue Number:	Please refer to Table 1
UMDNS Code:	14084
GMDN Code:	37469
EMDN Code:	R01038099
Basic UDI-DI:	Please refer to Table 1

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

Classification (MDR, Annex Ⅷ): IIa, Rule 5

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III) + Declaration of Conformity (Annex IV)

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

Regulation(s)

General applicable regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applicable Standard(s):
EN ISO 13485:2016+A11:2021/ EN ISO 14971:2019+A11:2021/ CEN ISO/TR 24971:2020/ EN ISO 14644-1:2015/ EN ISO 14644-2:2015/ EN ISO 14644-3:2019/ EN ISO 14644-4:2022/ EN ISO 14644-5:2004/ EN ISO 14644-7:2004/ EN ISO 14644-8:2022/ EN ISO 14644-9:2022/ EN ISO 14644-10:2022/ ISO 14644-12:2018/ EN ISO 14644-13:2017/ EN ISO 14644-14:2016/ EN ISO 14644-15:2017/ EN ISO 14644-16:2019/ EN ISO 14644-17:2021/ EN ISO 11135:2014+A1:2019/ EN ISO 11737-1:2018+A1:2021/ EN ISO 11737-2:2020/ EN ISO 11138-1:2017/ EN ISO 11138-2:2017/ EN 17141: 2022/ EN ISO 20417:2021/ EN ISO 15223-1:2021/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2023/ EN ISO 10993-12:2021/ EN ISO 10993-18:2020+A1:2023/ IEC 62366-1:2015+AMD1:2020/ IEC/TR 62366-2:2016/ ISTA 2A /EN

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15986:2011/ CEN ISO/TS 16775:2021/ EN 556-1:2001+AC:2006 / EN 556-2:2015/ EN 868-2:2017/ ASTM F1929-15/ EN ISO 11607-1:2020+A11:2022/ EN ISO 11607-2:2020+A11:2022/ ASTM F1980-16/ MDCG 2020-5/ MDCG 2020-6/ MEDDEV 2.7.1 rev.4/ MEDDEV 2.12-1 rev.8/ MEDDEV 2.12-2 rev.2/ MDCG 2020-7/ MDCG 2020-8/ SCHEER guidelines/ MDCG 2018-1 rev.4/ MDCG 2019-1

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	G10 038814 0092 Rev. 01
Expire date of the Certificate:	2028/5/15
Start of MDR CE Marking:	2023/12/12

Signature:

Name: Chen Yun Gui

Position: **Management Representative & PRRC**

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

Place, Date of Issue: **Guangzhou, 2023-12-12**

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

Table1

Type	Basic UDI-DI	Size	Wellead REF	Medline REF	DESCRIPTION
e Type with sleeve	69449327FA04B00CQ	6Fr	A04B05062F	844025A	Intubating Stylet, Size 6FR
		10Fr	A04B05101F	844040A	Intubating Stylet, Size 10FR
		14Fr	A04B05142F	844050A	Intubating Stylet, Size 14FR



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