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Document Nr.: WL-MDR-DOC-040/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, People Republic of China
SRN:	CN-MF-000006728
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	Silicone Tube
Intended Purpose:	For non-invasive medicinal application in hospitals and similar institutions, not as part of a supply line or a discharge to the body.
Type/ Size/ Catalogue Number:	Please refer to Table 1
EMDN Code:	A060102
Basic UDI-DI:	69449327FN01D00HN

Classification (MDR, Annex Ⅷ): **I (Non-sterile), Rule 1**

Conformity Assessment Route: **Technical Documentation (Annex Ⅱ and Annex Ⅲ) + Declaration of Conformity (Annex Ⅳ)**

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 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 ISO14971: 2019/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ EN ISO 15223-1:2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ ASTM F1980-16/ ISTA 2A/ IEC 62366-1:2015+AMD 1:2020/ SCHEER guidelines/ ISTA 2A/ ASTM F1980-16/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6

Signature:

Name: Chen Yun Gui

Position: **Management Representative**

Place, Date of Issue: **Guangzhou, 2022-12-22**

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

Table1 Catalogue Number

Size	Catalogue Number	ASID BONZ REF	DESCRIPTION
2.0x4.0	N01D040110	510204	Silicone Tube 15M, I.D.2mm, O.D.4mm
3.0x5.0	N01D040210	510305	Silicone Tube 15M, I.D.3mm, O.D.5mm
4.0x6.0	N01D040410	510406	Silicone Tube 15M, I.D.4mm, O.D.6mm
4.0x7.0	N01D040510	510407	Silicone Tube 15M, I.D.4mm, O.D.7mm
5.0x8.0	N01D040610	510508	Silicone Tube 15M, I.D.5mm, O.D.8mm
5.0x9.0	N01D040710	510509	Silicone Tube 15M, I.D.5mm, O.D.9mm
6.0x9.0	N01D041010	510609	Silicone Tube 15M, I.D.6mm, O.D.9mm
6.0x12.0	N01D041310	510612	Silicone Tube 15M, I.D.6mm, O.D.12mm
7.0x10.0	N01D041410	510710	Silicone Tube 15M, I.D.7mm, O.D.10mm
8.0x12.0	N01D041810	510812	Silicone Tube 15M, I.D.8mm, O.D.12mm
10.0x14.0	N01D042410	511014	Silicone Tube 15M, I.D.10mm, O.D.14mm

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