wellead 维力

WL-MDR-DOC-186-02/B

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:	Adapter Cable
Intended Purpose:	The Adapter Cable is used to connect Monitors and Temperature Sensor, such as Foley Catheter with Temperature Sensor.
Type/ Size/ Catalogue Number:	Table 1
EMDN Code:	K020102
Basic UDI-DI:	69449327FA11C00CK

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/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ IEC 60601-1:2005+A1:2012/ IEC 60601-1-2:2014

Signature:

Name: Chen Yun Gui

Position: **Management Representative**

Place, Date of Issue: **Guangzhou, 2025-3-26**

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

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Table1 Catalogue Number

Size	Catalogue Number	Medline REF	DESCRIPTION
Phone plug 6.35mm	O05A040105	646060A	D11D07-4-C05 Phone Plug 6.35mm Extension Tube, 5M
HP/ Philips round plug	O05A040205	646070A	D11D09-4-C05 HP Round Plug Extension Tube, 5M
Siemens round plug	O05A040305	646080A	D11D10-4-C05 Siemens Round Plug Extension Tube, 5M