wellead 维力

Document Nr.: WL-MDR-DOC-048-02-01/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:	Prefilled syringe with purified water or glycerin solution
Intended Purpose:	It is used to inflate the balloon of foley catheter.
Type/ Size/ Catalogue Number:	Prefilled syringes with 10% Glycerin solution, 10mL, Unoquip REF: 45000010
EMDN Code:	A020107
Basic UDI-DI:	69449327FF02C02EL

Classification (MDR, Annex Ⅷ): **Is, Rule 1**

Conformity Assessment Route: Quality Management System (Annex IX, Chapter I & III and section 4) + 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 ISO 20696:2018/ EN ISO 14971:2019/ CEN ISO/TR 24971:2020/ EN ISO 15223-1:2021/ EN ISO 20417:2021/ EN ISO 10993-1:2020/ EN ISO 10993-7:2008+AC:2009/ IEC 62366-1:2015+AMD1:2020/ SCHEER guidelines/ ISTA 2A/ ASTM F1980-16/ MEDDEV 2.7.1 rev.4/ MDCG 2020-5/ MDCG 2020-6/ EN ISO 11135:2014+A1:2019

Notified Body:	BSI Group The Netherlands B.V.
Identification number:	CE 2797
(EC) Certificate(s):	MDR 776669 R00
Expire date of the Certificate:	2027-12-18
Start of MDR CE Marking:	2022-12-19

Signature:

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

Name: Chen Yun Gui

Position: Management Representative & PRRC

Place, Date of Issue: Guangzhou, 2022-12-20

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