

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: Male External Catheter

Intended Purpose: Male External Catheters is designed for the management of male urinary incontinence.

Type: Type I, Type II, Type III

Size: 25mm, 28mm, 29mm, 30mm, 32mm, 36mm, 41mm

Catalogue No. Refer to Annex I

GMDN Code: 61504

UMDNS Code: 10765

EMDN Code: U070201

Basic UDI-DI: 69449327FF03A00ED

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

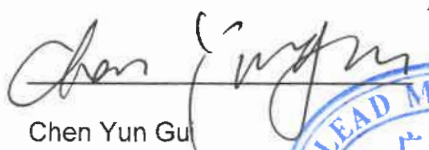
Conformity Assessment Route: **Technical Documentation (Annex II and Annex III) + Declaration of Conformity (Annex IV)**

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.

Signature:



Name:

Chen Yun Gu

Position:

Management Representative

Place, Date of Issue: **Guangzhou, 2022-07-13**



Annex I Catalogue No.

Size	Catalogue number			Inner diameter
Urimed® Vision Type 1 Standard	2962515	2962530	2962530D	25mm
Urimed® Vision Type 1 Standard	2962915	2962930	2962930D	29mm
Urimed® Vision Type 1 Standard	2963215	2963230	2963230D	32mm
Urimed® Vision Type 1 Standard	2963615	2963630	2963630D	36mm
Urimed® Vision Type 1 Standard	2964115	2964130	2964130D	41mm
Urimed® Vision Type 2 Specific	2982515	2982530	2982530D	25mm
Urimed® Vision Type 2 Specific	2982915	2982930	2982930D	29mm
Urimed® Vision Type 2 Specific	2983215	2983230	2983230D	32mm
Urimed® Vision Type 2 Specific	2983615	2983630	2983630D	36mm
Urimed® Vision Type 2 Specific	2984115	2984130	2984130D	41mm
Urimed® Vision Type 3 Ultra	2972515	2972530	2972530D	25mm
Urimed® Vision Type 3 Ultra	2972915	2972930	2972930D	29mm
Urimed® Vision Type 3 Ultra	2973215	2973230	2973230D	32mm
Urimed® Vision Type 3 Ultra	2973615	2973630	2973630D	36mm
Urimed® Vision Type 3 Ultra	2974115	2974130	2974130D	41mm