EC Declaration of Conformity

CE

Manufacturer:	Tianchang Ganor Medical Device Co., Ltd. Shuangliu Village, Datong Town, Tianchang City, 239361 Anhui, China
European Representative:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf Germany
Product names:	Urinary Drainage Bag: 2000ml, 1500ml, 1000ml
Model REF:	13800101, 13803412, 13853401, 13703412, 13850301, 13853101, 13853402
Classification:	Class I, Rule 1, Annex VIII of Medical Device Regulation (EU) 2017/745
UMDN code:	14298
GMDN codes:	58918, 58922
Basic UDI-DI：	697459245MBH001L5

Conformity Assessment Route: **Annex XI**

We herewith declare under our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following Medical Device Regulation (EU) 2017/745 and Standards. All supporting documentations are retained under the premises of the manufacturer.

Standard/Directive	Name of document
Regulation (EU) 2017/745	Medical Device Regulation
ISO 14971:2019	Medical devices - Application of risk management to medical devices.
ISO 15223-1:2016	Symbols for use in the labeling of medical devices
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Device-Part 10: Test for irritation and sensitization
EN ISO 8669-2:1996	Urine collection bags - Part 2: Requirements and test methods

Signature:
Name: Mr. Zhang, Jianqiang
Position: GM
Date and Place: 2021-05-25 Tianchang