Declaration of Conformity

MANUFACTURER:
Ucomfor Medical Co., Ltd.
Address: Rm1106, No.807 Zhaojiabang Road, 200030 Shanghai, PEOPLE'S REPUBLIC OF CHINA

AUTHORIZED REPRESENTATIVE:
Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg Germany

MEDICAL DEVICE:
Model Name: Urine Bag for single use(with/without gloves and straps)
Type or size: 350ML~5000ML
Classification: (MDD, Annex IX Rule I) I sterile
UMDNS code: 14298
Conformity Assessment Procedure: Annex V, Annex VII

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer (head of Quality department). The declaration of conformity is issued under our sole responsibility..

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

Applicable standards: refer to attached list

Notified Body: TÜV SÜD Product Service GmbH
Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany
Identification No.: 0123
EC Certificate(s): G2S 060204 0041 Rev.00
EC certificate(s) valid until: 2021-12-20

Shanghai CHINA

(Place and date of issue of this certificate)*

Ava Wu Management Representative
(Signature and title of authorized person)*

Effective

EU and International Standards

The following EU and International Standards are listed in order for corresponding to the 13 items in the Basic Requirement Checklist.

No.	File No.	Version Number	File Name
1	ISO 13485	2016	Medical Devices –Quality Management Systems- Requirements for Regulatory Purposes
2	ISO 14971	2007	Medical Devices-Application of risk management to Medical Devices
3	ISO 11135-1	2007	Sterilization of health care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for Medical devices
4	ISO 11737-1	2006	Sterilization of Medical Devices –Microbiological methods-Part 1: Determination of Population of Microorganisms on products
6	ISO 11737-2	2009	Sterilization of Medical Devices –Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
7	ISO 11607-1	2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
8	ISO 11607-2	2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
9	ENISO 15223-1	2012	Medical device-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements Remains Current [Superseded: CEN EN 980]
10	ASTM F1980	2007 (2011)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
11	ASTM F88	2009	Standard Test Method for Seal Strength of Flexible Barrier Materials
12	ASTM F1929	2012	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
13	ASTM D4169	2009	Standard Practice for Performance Testing of Shipping Containers and Systems.
14	ISO 10993-7	2008	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
15	ISO 8669-2	1996	Urine collection bags-part 2: Requirements and test methods