

Declaration of Conformity

Manufacturer: **Huaian Medicom Medical Technology Co.,Ltd**
No.123,Meicheng West Road ,Huaian223002 ,Jiangsu, China.

European Representative: **Caretechion GmbH**
Niederrheinstr. 71, 40474 Düsseldorf, Germany

Product Name: **Urine drainage bag**

Models: **Adult pull-push valve: 2000ml;1500ml;1000ml;**
Adult T type valve: 2000ml;1500ml;1000ml
Adult Without valve: 2000ml;1500ml;1000ml
Pediatric: 200ml;100ml

UMDN Code: **14298**

Classification (MDD, Annex IX): **Is, Rule 1.**

Conformity Assessment Route: **Annex VII+Annex V**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2S 004080 0003 Rev. 01

Expire date of the Certificate: 2023-12-26

Start of CE Marking: Not Yet

Place, Date of Issue: HuaiAn, 2020-03-19

Signature:

Name:

Position:

