

Manufacturer's EU Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Medeco BV
Chamber of Commerce Registration # 23038479

Issuer's address : Alexander Flemingstraat 2
3261MA Oud Beijerland
The Netherlands

Object of the declaration : Urinary drainage products

Single registration number : NL-MF-000001628

Classification : REGULATION (EU) 2017/745 Annex VIII, see attached Product list

Conformity assessment : REGULATION (EU) 2017/745 Annex II and Annex III

Validity : This declaration of conformity is valid at least during the lifetime of the products concerned. The declaration will be updated in case of changes in the product range and after issuance of a new product or quality system certificate.

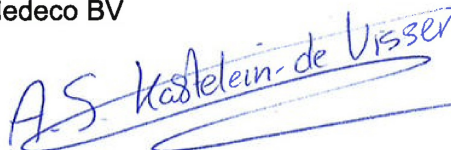
Hereby Medeco BV declares that the distributed products as specified in the annexed product list meet the provisions of the Council Regulation 2017/745 of 5 April 2017 on Medical Devices and comply to all harmonized standards which are applicable to the products, as published in the Official Journal of the European Union. Medeco BV further declares that it is exclusively responsible for this declaration of conformity.

This documentation is supported by the Quality Management System certification based on the harmonized standard EN ISO 13485:2016, Quality Management System Certificate with reference numbers: MD 644507, issued for the 1st time on 20 June 2016, and delivered by BSI. The applied standards for this family of products is maintained in the Technical Dossier.

Oud Beijerland, 29 April 2021

Name : A.S. Kastelein – de Visser
Function : QA Manager
Medeco BV

Signature :



Product list related to DoC MD Class I – Urinary drainage products

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
8080	URINE LEG BAG HOLDER	I	1	18756INCCCT0499L5
2019	CURION URINE BEDBAG 2000ML 90CM cross valve	I	1	18756CUBA06030388
2021	CURION URINE LEGBAG 500ML 10CM cross valve	I	1	18756CUBA06030388
2022	CURION URINE BEDBAG 2000ML 120CM cross valve C4	I	1	18756CUBA06030388
2025	CURION URINE LEGBAG 500ML 45CM cross valve	I	1	18756CUBA06030388
2027	CURION URINE LEGBAG 500ML 60CM cross valve	I	1	18756CUBA06030388
2040	CURION SOFT CARELINE URINE LEGBAG 500ML 10CM cross valve cut to fit	I	1	18756CUBA06030388
2054	CURION SOFT URINE LEGBAG 500 ml multi chamber 15 cm tube cut to fit	I	1	18756CUBA06030388
2054K	CURION SOFT URINE LEGBAG 500 ml multi chamber 15 cm tube cut to fit	I	1	18756CUBA06030388
2055	CURION SOFT URINE LEGBAG 500 ml multi chamber 60 cm tube cut to fit	I	1	18756CUBA06030388
2055K	CURION SOFT URINE LEGBAG 500 ml multi chamber 60 cm tube cut to fit	I	1	18756CUBA06030388
2056	CURION SOFT URINE LEGBAG 750 ml multi chamber 60 cm tube cut to fit	I	1	18756CUBA06030388
2056K	CURION SOFT URINE LEGBAG 750 ml multi chamber 60 cm tube cut to fit	I	1	18756CUBA06030388
2057	CURION SOFT URINE BEDBAG 1500 ml multi chamber 120 cm tube cut to fit	I	1	18756CUBA06030388
2057K	CURION SOFT URINE BEDBAG 1500 ml multi chamber 120 cm tube cut to fit	I	1	18756CUBA06030388
2060	CURION SOFT URINE BEDBAG 2000 ml multi chamber 140 cm tube cut to fit	I	1	18756CUBA06030388
2061	CURION URINE LEGBAG 750ML 10CM cross valve	I	1	18756CUBA06030388
2065	CURION URINE LEGBAG 750ML 45CM cross valve	I	1	18756CUBA06030388
2072	CURION SOFT URINE LEGBAG 500 ml multi chamber 6 cm	I	1	18756CUBA06030388
602000	CURION URINE BEDBAG 2000ML 130CM cross valve CC	I	1	18756CUBA06030388
8044	LEG STRAPS Velcro	I	1	18756INCCCT0499L5
8048	LEG STRAPS Velcro / button	I	1	18756INCCCT0499L5
8084	FIXETTE URINE LEG BAG HOLDER S	I	1	18756INCCCT0499L5
8086	FIXETTE URINE LEG BAG HOLDER M	I	1	18756INCCCT0499L5
8088	FIXETTE URINE LEG BAG HOLDER L	I	1	18756INCCCT0499L5
8090	FIXETTE URINE LEG BAG HOLDER XL	I	1	18756INCCCT0499L5
8758	CURION URINE BEDBAG 2000ML 110CM cross valve	I	1	18756CUBA06030388

Product list related to DoC MD Class I – Urinary drainage products

Ref Nr	Article Description	Class	Rule	BASIC UDI-DI
8011	CURION URINE BEDBAG 1500ML 90CM	I	1	18756CUBA06030388
8015	CURION URINE BEDBAG 1500ML 10CM	I	1	18756CUBA06030388
8019	CURION URINE BEDBAG 2000ML 90CM push pull	I	1	18756CUBA06030388
8030	CURION URINE LEGBAG 500ML 10CM push pull	I	1	18756CUBA06030388
8032	CURION URINE LEGBAG 750ML 10CM	I	1	18756CUBA06030388
8034	CURION URINE LEGBAG 500ML 45CM push pull	I	1	18756CUBA06030388
8036	CURION URINE LEGBAG 500ML 60CM push pull	I	1	18756CUBA06030388
8042	URINE BAG EXTENTION TUBE 60CM	I	1	18756INCCCT0499L5
8070	CURION URINE BEDBAG 1500ML 90CM	I	1	18756CUBA06030388
8072	CURION URINE BEDBAG 1500ML 110CM	I	1	18756CUBA06030388
8074	CURION URINE BEDBAG 1500ML 10CM	I	1	18756CUBA06030388
8078	CURION URINE BEDBAG 2000ML 90CM push pull	I	1	18756CUBA06030388