

Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Medeco BV
Issuer's address : Chamber of Commerce Registration # 23038479
Alexander Flemingstraat 2
3261MA Oud Beijerland
The Netherlands

Object of the declaration : Urinary bags

UMDNS Code : See attached Product list

Classification : According to MDD Annex IX, see attached Product list

Conformity assessment : MDD Annex II

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 MDD 93/42/EEC Medical Device Directive: Council Directive 93/42/EEC concerning medical devices June 14th, 1993 as amended by directive 2007/47/EC 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.

Additional information

Notified Body : BSI, Notified Body Number 2797
Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, The Netherlands

CE certificate : CE 607662

First Issue Date certificate : 24 June 2016

Validity : 26 May 2024

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 UK. The applied standards for this family of products are maintained in the Technical Dossier.

Oud Beijerland, 3 March 2021

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

Signature :

Productlist related to DoC CE607662U

| UMDNS | REF nr | Article Nr | Name | Class | Rule |
|--------|--------|------------|--------------------------------|-------|------|
| 14-298 | 2020 | 3015201 | CURION URINE BAG C4 2000ML *S* | Is | 2 |
| 14-298 | 2075 | 3015258 | CURION URINE LEG BAG 500ML *S* | Is | 2 |

3-3-2021
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