

11 June 2019

Declaration of Conformity

Product: Depend Adult Incontinence Products

Product Codes: See below

Competent Authority: CIBG, Ministry of Health, Welfare and Sport,

Netherlands

GMDN 11-239 Nappy, Adult 11239 Nappy, Adult Manufacturer: Kimberly-Clark B.V.

Copernicuslaan 35, 6716 BM Ede, Netherlands

Classification Rule(s): ONE

CE-Certification of Medical Devices class I, as per Annex IX of Directive 93/42/EEC, amended by Directive 2007/47/EC.

Kimberly-Clark Disposable Incontinence Products, models:

Product Code	Description
1970541	Depend® Comfort Protect Super S/M Female 10x6 FR
1971641	Depend® Comfort Protect Super L Female 9x6 FR
1980541	Depend® Comfort Protect Super S/M Male 10x6 FR
1981531	Depend® Comfort Protect Super L/XL Male 9x6 FR
1972561	Depend® Pants Normal S/M Female 10x6 EU
1973561	Depend® Pants Normal L Female 9x6 EU
1982561	Depend® Pants Normal S/M Male10x6 EU
1983561	Depend® Pants Normal L/XL Male 9x6 EU
1970561	Depend® Pants Super S/M Female 10x6 EU
1971561	Depend® Pants Super L Female 9x6 EU
1979561	Depend® Pants Super XL Female 9x6 EU
1980561	Depend® Pants Super S/M Male 10x6 EU
1981541	Depend® Pants Super L/XL Male 9x6 EU
1971391	Depend® Pants Normal M/L Female 10x6 EE
1971531	Depend® Pants Normal L/XL Female 9x6 EE
1971631	Depend® Pants Normal L/XL Male 9x6 EE
1970591	Depend® Pants Super S/M Female (10x6)x1 MP
1971541	Depend® Pants Super L Female (9x6)x1 MP
1981591	Depend® Pants Super L/XL Male (9x6)x1 MP
1970491	Depend® Pants Super S/M Female 10x3 GB Pst Bx

1980491	Depend® Pants Super S/M Male 10x3 GB Pst Bx
1971141	Depend® Pants Super L Female 9x3 GB Pst Bx
1979491	Depend® Pants Super XL Female 9x3 GB Pst Bx
1981501	Depend® Pants Super L/XL Male 9x3 GB Pst Bx
1971721	Depend® Pants Normal S/M Female 10x6 TR
1971821	Depend® Pants Normal M/L Female 9x6 TR
1971921	Depend® Pants Normal L/XL Male 8x6 TR

We hereby declare that the above mentioned devices comply with the European Medical Devices Directive 93/42/EEC, and the Directive 2007/47/EC, and are in accordance with Annex VII of Directives 93/42/EEC and 2007/47/EC, supported by the Conformity Assessment Procedure, and adhering to the essential requirements in accordance with Annex I of Directives 93/42/EEC and 2007/47/EC.

This declaration is made on the basis of an implemented documented Quality Management System, and is also based on the existing Technical Documentation as per Annex VII, paragraph 3. CE marking carried out as per Annex XII of Directives 93/42/EEC and 2007/47/EC. This declaration is valid for the above product in its original, unmodified packaging.

Kimberly-Clark B.V. Copernicusiaan 35,

6716 BM Ede, Netherlands Regulatory Affairs

Kimberly-Clark B.V.

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Global Regulatory Affairs

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