Medical Device Declaration of Conformity

Version: Revision Date: Date of First Issue: 1.0 06.05.2021 06.05.2021



TD: 1227

Supplier and Product Details	
Manufacturer	Kimberly-Clark B.V.
	Copernicuslaan 35, 6716 BM
	Ede, Netherlands
Product Name	Depend® Pants High Rise Super Male
	(S/M, L/XL)
Product Codes	1948021, 1985021, S1948, S1985
Competent Authority	CIBG, Ministry of Health, Welfare and Sport,
	Netherlands
UMDN	11-239 Nappy, Adult
GMDN	11239 Nappy, Adult
Classification Rule	One
Basic UDI	8710461ADULTPANTS4R

This EU declaration of conformity is issued under the sole responsibility of Kimberly Clark B.V. being a manufacturer.

We hereby declare that the above mentioned devices comply with the European Medical Devices Regulation 2017/745, and are in accordance with Article 52-7 of Medical Devices Regulation 2017/745, supported by the Conformity Assessment Procedure, and adhering to the general safety and performance requirements in accordance with Annex I of Regulation 2017/745. 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 II and III. CE marking carried out as per Annex V of Regulation 2017/745. This declaration is valid for the above product in its original, unmodified packaging.

Ozlem Ariz
Regulatory Affairs Leader
Revision Date:
06.05.2021