Medical Device Declaration of Conformity



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

TD: 1241

Supplier and Product Details		
Manufacturer	Kimberly-Clark B.V. Copernicuslaan 35, 6716 BM Ede, Netherlands	
Product Name	Depend [®] Pads for Men Guards	
Product Codes	1590631, 20057966, S1590	
Competent Authority	CIBG, Ministry of Health, Welfare and Sport, Netherlands	
UMDN	16-498 Incontinence Pants and Liners	
GMDN	35817 Incontinence pants. Liner	
Classification Rule	One	
Basic UDI	8710461ADULTPADSFV	

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	Deleeu	Revision Date: 06.05.2021
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