Medical Device Declaration of Conformity

Version:5 Revision Date: 27.06.2025 Date of First Issue: 06.05.2021 TD:00106

Supplier and Product Details	
Manufacturer / Place of Issue	Kimberly-Clark B.V. Copernicuslaan 35, 6716 BM Ede, Netherlands
Product Name	DryNites Pyjama Pants, 4-7 yrs, 8-13 yrs, 13+ yrs Boys, Girls
Product Codes	2254024 2154034 2253033 2253024 2154046 2153046 2244023 2244013 2243023 2243013 2152152 2151142 2252142 2252102 2251024 2251132 2242022 2241012 2364002 2363002 2264012 2164042 2263012 2163042 S2141 S2142 S2143 S2144 S2263 S2264 2242021 2244022 2264011 2241011 2243022 2263011
Competent Authority	CIBG, Ministry of Health, Welfare and Sport, Netherlands
SRN	NL-MF-000004367
EMDN	T04010102 Profiled Nappies
Classification Rule	One
Basic UDI-DI	8710461CHILDPANTSTQ
Intended Use	Drynites Pyjama Pants are incontinence pants designed for children above 5 years old, who suffer from ENURESIS (bed-wetting) to absorb involuntarily lost urine and to protect the child's garments and bedding. While bedwetting is a normal condition until the age of 5, it is considered a disease after the age 5 called ENURESIS.

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 Sr Regulatory Affairs Manager, Europe		Revision Date: 27.06.2025

Heruntergeladen von Gast (IP 216.73.217.12) am 09.11.2026 um 10:48 Uhr · sana.swiss