

EC Declaration of Conformity



Manufacturer:	Procter & Gamble Technical Centres Limited, The Heights, Brooklands, Weybridge, Surrey, KT13 0XP, United Kingdom	
	SRN: GB-MF-000017862	
Authorised Representative:	Procter & Gamble Service GmbH Sulzbacher Str. 40 65824 Schwalbach a. Ts. Germany	
	SRN: DE-AR-000016615	
Product name:	Bedwetter Pants	
European Medical Devices Nomenclature (EMDN):	T04010102 – Shaped Incontinence Nappies	
Trade (brand) name:	<ul style="list-style-type: none"> • Ninjamas/Pyjama Pants • Dodot/Happyjama 	
Product reference:	Global Medical Devices Nomenclature System (GMDN) name/code:	Infant nappy/35008
	Basic UDI-DI:	8001090childincoFK
Intended Purpose:	Bedwetter Pants is an absorbent disposable single-use underwear pant developed for children suffering from nocturnal enuresis (nighttime bedwetting). Bedwetter Pants helps manage and contain urination gushes overnight.	
Class:	I	
Common Specification:	Not Applicable	

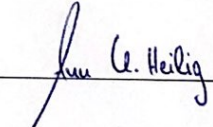
We hereby declare that the above mentioned medical device complies with all the provisions of Regulation (EU) 2017/745 which apply, and accordingly, the **CE** mark will be placed on all production batches placed on the market in the member states of the European Union and EFTA as defined in this declaration under Annex II and III. This Declaration of Conformity is only valid in connection with the release documents for the respective batch of produced devices. All supporting documentation is retained by the manufacturer. The declaration of conformity is issued under the sole responsibility of the manufacturer.

Schwalbach

Place

02.06.2023
Date

Signature


Dr. Ann Kathrin Heilig, Regulatory Affairs
On behalf of
Procter & Gamble Technical Centres Ltd.