Ropox A/S
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SRN: DK-MF-000020145

EN EU Declaration of Conformity

EN	This declaration of conformity issued under the sole responsibility of ROPOX A/S, certifies that the **ROPOX Vario Changing Bed**, conforms with the relevant legislation.

EN	**Intended use**	Vario is a fixed, height adjustable & foldable changing bed that can be used for care of children and adults up to 200 kg. The changing bed is intended for use in private homes, institutions, day care centers and similar institutions and for people with physical or mental disabilities. The product is designed to provide optimum working conditions for caregivers. The changing bed can be used in both dry and wet rooms (conditions), but must not be used as a shower bed. The height of tabletop (changing bed) can be adjusted infinitely from 30-100 cm using the hand control and can be folded up for spare saving when not in use.
	MDR Classification	This product is classed as a Class I product by Rule 13 (EU Regulation 2017/745 Annex VIII - Chapter III) and Class I by rule 12 in the 93/42 EEC due to being an active device. The device is normally intended for long term accumulated use (more than 30 days). This is a non-sterile device.

Basic UDI-DI	**57075810012R2**
GMDN	**43600**

REF

40-30604	**EN**	ROPOX Vario Changing Bed	120x70cm	Without bed guard
40-30606		ROPOX Vario Changing Bed	140x70cm	Without bed guard
40-30608		ROPOX Vario Changing Bed	160x70cm	Without bed guard
40-30610		ROPOX Vario Changing Bed	180x70cm	Without bed guard
40-30611		ROPOX Vario Changing Bed	190x70cm	Without bed guard
40-30804		ROPOX Vario Changing Bed	120x70cm	With bed guard
40-30806		ROPOX Vario Changing Bed	140x70cm	With bed guard
40-30808		ROPOX Vario Changing Bed	160x70cm	With bed guard
40-30810		ROPOX Vario Changing Bed	180x70cm	With bed guard
40-30811		ROPOX Vario Changing Bed	190x70cm	With bed guard

EN	The undersigned hereby declares that the product complies with relevant requirements in the following regulation/directives and standards.	
	Legislation Conformity	• European Medical Device Regulation 2017/745 (articles 10, 19 and Annex IV) • European Directive 2011/65/EU, RoHS

EN	Harmonized Standard	**EN ISO 9001:2015**	Quality management systems
	Harmonized Standard	**EN ISO 14971:2019**	Application of risk management to medical devices
	Harmonized Standard	**EN ISO 10993-1:2009**	Biological evaluation of medical devices
	Harmonized Standard	**IEC 60601-1:2005**	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
	Harmonized Standard	**IEC 60601-1-2:2014**	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test
EN	Non harmonized Standard	**ISO 17966:2016**	Assistive products for personal hygiene that supports users – Requirements and test methods

Naestved, 30-05-2023

Nils Bundgaard
CEO