

Declaration of Conformity TOPRO Troja Walker2

Document ID:	6338	Document type:	Declaration of conformity
Revision:	3	Document owner:	Quality
Prepared date:	10.02.2025	Prepared by:	Cosmin Cioroiu
Last revised:	10.02.2025	Revised by:	Cosmin Cioroiu
Approved:	Yes	Approved by:	Nicolai Skarsgård
Approved date:	10.02.2025		

Published: 10.02.2025

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.
This DoC is designed according to Annex IV of Medical Device Regulation (EU) 2017/745.

As Legal Manufacturer, we

TOPRO Industri AS•
Rambekkveien 1
NO-2816 Gjøvik
NORWAY

SRN: NO-MF-000003447

hereby declare under our sole responsibility that the following CE marked device(s)

Product/trade name(s)	TOPRO Troja Walker ²	
Intended Purpose	The device shall give support to users with reduced balance and/or reduced walking ability	
Model Number(s) and Name(s)	815430	TOPRO Troja Walker ² M
	815440	TOPRO Troja Walker ² S
	815450	TOPRO Troja Walker ² X
Variant Number(s)	135000 / 135400 / 136000 / 136400	
Basic UDI-DI	705432TWA2012Y3	

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

The object of the Declaration described above is in conformity with the following regulations and standards:

EU Regulation	Medical Device Regulation (EU) 2017/745
NS-EN ISO 9999:2022	Assistive products - Classification and terminology
NS-EN ISO 28156:2022	Assistive products - General requirements and test methods
NS-EN 1985:1998	Walking aids - General requirements and test methods
NS-EN ISO 11199-3:2005	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables
NS-EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer

TOPRO hereby confirm that all models/variants and their original accessories are produced and tested in accordance the above mentions regulations and standards. All the technical documentation for the device(s) are stored at the manufacturer.

The user manuals are attached with the products.

GJØVIK/ 10.02.2025

Nicolai Skarsgård / CEO

Document history

Replacements

DATE	HISTORY	REV	SIGN
2021.05.10	Replaces Doc.Id: 6039		ÅÅ

Changes

DATE	HISTORY	REV	SIGN
2023.02.06	Updated list of standards and variant numbers	2	LB