Declaration of Conformity TOPRO Troja Original

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Approved:	**Yes**	Approved by:	**Nicolai Skarsgård**
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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 Original	
Intended Purpose	The device shall give support to users with reduced balance and/or reduced walking ability	
Model Number(s) and Name(s)	815400	TOPRO Troja Original M
	815410	TOPRO Troja Original S
	815420	TOPRO Troja Original X
Variant Number(s)	110000 / 110060 / 110070 / 110200 / 110201 / 110300 / 110301 / 110302 / 110303 / 110304 / 110400 / 110460 / 110600 / 110700 / 110701 / 110704 111000 / 111060 / 111200 / 111201 / 111300 / 111301 / 111304 / 111400 / 111460 / 111600 / 111700 / 111701 / 111704 112000 / 112060 / 112301 / 112304 / 112400 / 112700 / 112701 / 110500 / 110570 / 110560 / 110510 / 111500 / 111570 / 111560 / 111510 / 112500 / 112560 / 130400 / 131400 / 130460 / 131460	
Basic UDI-DI	705432TOR81474T	

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 11199-2:2021	Assistive products for walking manipulated by both arms - Requirements and test methods – Part 2: Rollators
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/ 02.05.2025

Nicolai Skarsgård / CEO

Document history

Replacements

DATE	HISTORY	REV	SIGN
2021.05.10	*Replaces Doc. ID:6038*	*1*	*ÅA*

Changes

DATE	HISTORY	REV	SIGN
12/01/2023	*Update ISO standard NS-EN ISO 11199-2:2021*	*2*	*CC*
03/02/2023	*Updated with new variant numbers and home page address*	*3*	*LB*
19/04/2023	*Updated list of standards*	*4*	*LB*
21/05/2024	*Added new variant numbers*	*5*	*LB*
2025.02.10	*Changed address*	*6*	*CC*
2025.04.15	*Added new variant numbers (BS)*	*7*	*SK*
2025.05.02	*Added new variant numbers (Original Plus)*	*8*	*SK*