Declaration of Conformity TOPRO Olympos ATR

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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 Olympos ATR	
Intended Purpose	The device shall give support to users with reduced balance and/or reduced walking ability	
Model Number(s) and Name(s)	814300	TOPRO Olympos ATR M
	814305	TOPRO Olympos ATR S
	814320	TOPRO Olympos ATR M Slim
	814325	TOPRO Olympos ATR S Slim
	815600	TOPRO Olympos ATR M (SE)
	815610	TOPRO Olympos ATR S (SE)
	815620	TOPRO Olympos ATR M Slim (SE)
	815630	TOPRO Olympos ATR S Slim (SE)
Variant Number(s)	120000 / 120060 / 120070 / 120200 / 120210 / 120240 / 120260 / 120270 / 120301 / 120302 / 120303 / 120400 / 120600 / 120610 / 120640 / 120660 / 120670 / 120701 121000 / 121060 / 121070 / 121200 / 121210 / 121240 / 121260 / 121270 / 121400 / 121600 / 121610 / 121660 / 121670 122200 / 122260 / 122270 / 122301 / 122400 / 122600 / 122660 / 122670 / 122700 / 122701 / 122704 128000 / 128001 / 128400 / 120800 / 120870 / 120860 / 120810 / 121800 / 121870 / 121860 / 121810 / 122500 / 122570 /122560 / 122510	
Basic UDI-DI	705432OLY814334	

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 21856:2022	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/ 15.04.2025

Nicolai Skarsgård / CEO

Document history

Replacements

DATE	HISTORY	REV	SIGN
03.05.2021	*Replaces doc 6247*		*ÅA*

Changes

DATE	HISTORY	REV	SIGN
2021.05.12	*Added 815600, 815610, 815620 and 815630*		*ÅA*
2022.05.23	*Updated to new version of NS-EN ISO 11199-2:2021*	*1*	*ÅA*
2023.02.06	*Updated variant numbers and list of standards*	*2*	*LB*
2024.05.21	*Updated variant numbers*	*3*	*LB*
2025.02.10	*Changed Address*	*4*	*CC*
2025.04.15	*Added new variants*	*5*	*SK*