Declaration of Conformity TOPRO Taurus E

Document ID:	**6347**	Document type:	**Declaration of conformity**
Revision:	**2**	Document owner:	**Quality**
Prepared date:	**06.02.2023**	Prepared by:	**Cosmin Cioroiu**
Last revised:	**19.04.2023**	Revised by:	**Cosmin Cioroiu**
Approved:	**Ja**	Approved by:	**Daria Kovalevskaya**
Approved date:	**03.05.2023**		

Published: 03.05.2023

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
Rambekkvegen 5
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 Taurus E	
Intended Purpose	The device shall give support to users with reduced balance and/or reduced walking ability	
Model Number(s) and Name(s)	814790	TOPRO Taurus E Basic
	814789	TOPRO Taurus E Premium
Variant Number(s)		
Basic UDI-DI	705432TAE1479RW	

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 11199-3:2005	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables
IEC 60601-1:2012 (Edition 3.1) - Partial evaluation of IEC 62304: 2006 + A1: 2015 required by IEC 60601-1:2012 (ed.3.1) - IEC 60601-1-6:2010 + A1: 2013 - IEC 62366: 2007 + A1: 2014 - IEC 60601-1-11:2015	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014 - Clause 12 of IEC 60601-1-11:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 / 2023.04.19

Daria Kovalevskaya / Quality Manager

Document history

Replacements

DATE	HISTORY	REV	SIGN
2021.05.10	*Replaces Doc.Id:5199*	*4*	*ÅA*

Changes

DATE	HISTORY	REV	SIGN
2023.02.06	*Updated list of standards*	*2*	*LB*