# Declaration of Conformity TOPRO Taurus E

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| Document ID: | **6347** | Document type: | **Declaration of conformity** |
| Revision: | **4** | Document owner: | **Quality** |
| Prepared date: | **20.05.2025** | Prepared by: | **Cosmin Cioroiu** |
| Last revised: | **20.05.2025** | Revised by: | **Silvio Koch** |
| Approved: | **Yes** | Approved by: | **Silvio Koch** |
| Approved date: | **20.05.2025** | | |

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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)

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|---|---|
| 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<br>814789 – TOPRO Taurus E Premium<br>815710 – TOPRO Taurus E<br>815711 – TOPRO Taurus E flat pack |
| 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:

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|---|---|
| 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)<br>- Partial evaluation of IEC 62304: 2006 + A1: 2015 required by IEC 60601-1:2012 (ed.3.1)<br>- IEC 60601-1-6:2010 + A1: 2013<br>- IEC 62366: 2007 + A1: 2014<br>- IEC 60601-1-11:2015 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2: 2014<br>- 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/ 20.05.2025

Silvio Koch / Product 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* |
| *2025.02.10* | *Change Address* | *C* | *CC* |
| *2025.05.20* | *New Variant number added* | *4* | *SK* |