

# EU Declaration of Conformity

## Samsvarserklæring

We **Hepro AS**  
**Tømmerveien 10,**  
**8250 Rognan, Norway**

**Phone: +47 46745555**  
**Web: [www.hepro.no](http://www.hepro.no)**

hereby declare that this DoC is issued under our sole responsibility as a manufacturer, and belongs to the following product(s):

*erklærer herved, på eget ansvar, at vi som produsent har utstedt denne samsvarserklæring for følgende produkt(er):*

<b>Product name</b>	<i>Hepro Trolley</i>
<b>Basic UDI-DI</b>	<i>7070419H1112U01TR24P5</i>

<b>Art. No.</b>	<b>Name/model</b>	<b>Description</b>	<b>UDI-DI</b>
35600	Hepro Trolley	Trolley table	07070419356008
35610	Hepro Trolley	Trolley table	07070419356107

The product(s) mentioned above is classified as Class 1 and comply with the following directives and regulations:

*Produktet / produktene nevnt ovenfor er klassifisert som risikoklasse 1 og oppfyller følgende direktiver og forskrifter*

<b>Directive/ regulation</b>	<b>Description</b>
EU 2017/745	Regulation on Medical Devices
ISO 14971:2019	Risk Management
NS-EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

For the evaluation of the compliance with these Directives and Regulations, the following harmonized standards/ requirements have been applied:

*Følgende harmoniserte standarder / krav er brukt for evaluering av samsvar med disse direktiver og forskrifter:*

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Standard	Description
NS-EN 12182:2012	Assistive products for persons with disability – General requirements and test methods

Certificate No. 010 issued by Kiwa Technological Institute certifies conformity with the management system requirements of NS-EN-ISO 9001:2015, Quality management systems, and NS-EN ISO 14001:2015, Environmental management systems.

*Sertifikat nr. 010 utstedt av Kiwa Teknologisk Institutt viser godkjent overensstemmelse med styringssystemkravene i henhold til NS-EN-ISO 9001:2015, Ledelsessystemer for kvalitet, og NS-EN ISO 14001:2015, Ledelsessystemer for miljø.*

As a result of the correspondence with the mentioned norms, the product is entitled to CE approval.

*Som et resultat av samsvar med de nevnte normer, kvalifiserer produktet til å bli CE-merket.*

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#### Actor Identification

<b>Role:</b>	Manufacturer
<b>Actor ID/ SRN:</b>	NO-MF-000007973
<b>Country</b>	Norway
<b>Actor/ Organisation name</b>	Hepro AS (EN)
<b>Abbreviated name:</b>	Hepro AS (EN)
<b>VAT information</b>	Yes
<b>VAT number:</b>	NO937162103MVA

Rognan, 19.04.2024

*Geir Tore Jakobsen*

Geir Tore Jakobsen  
Managing Director/ CEO

Picture(s) of product(s):



Hepro Trolley (35600)  
75mm castors/75mm trinser



Hepro Trolley (35610)  
100mm castors/100mm trinser