

EU Declaration of Conformity

Samsvarserklæring

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

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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):

Product name	<i>Hepro G2 Sadel</i>
Basic UDI-DI	<i>7070419H1111U12SA24LE</i>

Art. No.	Name/model	Description	UDI-DI
32952	Hepro G2 Sadel Liten	Standing stool with manuel seatlift, backrest and seat rotation	07070419329521
32953	Hepro G2 Sadel Stor	Standing stool with manuel seatlift, backrest and seat rotation	07070419329538

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

Directive/ regulation	Description
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

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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:

Standard	Description
NS-EN 1335-2:2018	Office furniture - Office work chair – Part 2: Safety requirements
NS-EN 1021-1:2014	Assessment of the ignitability of upholstered furniture – Part 1: Ignition source smoldering cigarette
NS-EN 1021-2:2014	Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent

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

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

Rognan, 19.04.2024

Geir Tore Jakobsen

Geir Tore Jakobsen
Managing Director/ CEO

Picture(s) of product(s):



Hepro G2 Sadel Liten



Hepro G2 Sadel Stor