

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	Gripo
Basic UDI-DI	07070419352000

Art.No.	Name/model	Description	UDI-DI
35200	Gripo	Height 2,1 - 3,0 m	07070419352000
35210	Gripo Lang	Height 2,6 - 3,4 m	07070419352109
35202	Gripo Spesial	Height < 2,1 m	07070419352024

The product(s) mentioned above is classified as risk class 1 and complies 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

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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:

ISO 21856:2022 - Assistive products - General requirements and test methods	
	5.3 Biocompatibility and toxicity test 17.2 Static forces
ISO 10993-10	Maximization Sensitization test
ISO 10993-5	In Vitro Cytotoxicity test
ISO 10993-10	Skin irritation test

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/ Organization name	Hepro AS (EN)
Abbreviated name:	Hepro AS (EN)
VAT information	Yes
VAT number:	NO937162103MVA

Rognan, 18.02.2025

Geir Tore Jakobsen

Geir Tore Jakobsen
Managing Director/ CEO

Picture(s) of product(s): Gripo support pole

