

Samsvarserklæring (Declaration of Conformity)

HEPRO

Produsent (manufacturer)	Hepro AS
Organisasjonsnr.	937 162 103
Adresse (address)	Øvermoan 9, 8250 Rognan

Hepro AS erklærer på eget ansvar at følgende produkter nevnt i Tabell 1, inkludert tilbehør, er utviklet, produsert og testet i samsvar med standarder og direktiver nevnt i Tabell 2 og Tabell 3.

Hepro AS declares with complete responsibility that the following products mentioned in Table 1, accessories included, are developed, produced and tested in conformity to regulations and requirements mentioned in Table 2 and Table 3.

Gripo Gripo

Risiko klasse 1 Risk class 1

Tabell 1: Modeller (Table: 1 Models)

Art.nr.	Article name	Basic UDI-di
35100	Gripo	07070419351003

Tabell 2: Standard og direktiv (Table 2: Standards and Directives)

Standard/direktiv (Standard/directive)	Beskrivelse (Description)	Gjelder (Applies)
745/2017	EU MDR	All models
ISO 14971	Medical devices – Application of risk management to medical devices	All models

Tester utført av akkrediterte laboratorier for godkjenning:

Tests carried out by accredited laboratories for approval:

Tabell 3: Tester (Table 3: Tests)

Standard	Test	Resultat (Result)
EN 12182:2012	Static and dynamic forces	Passed
ISO 10993-10	Maximization Sensitization test	Passed
EN 12182:2012	Biocompatibility and toxicity test	Passed
ISO 10993-5	In Vitro Cytotoxicity test	Passed

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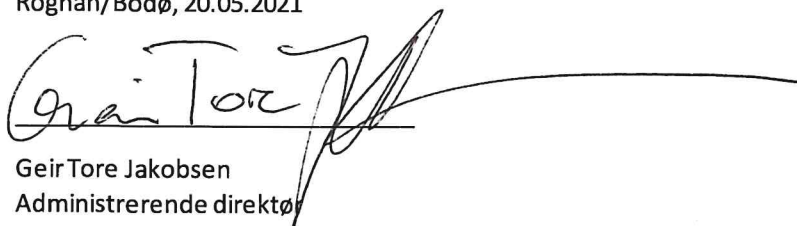
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ISO 10993-10	Skin irritation test	Passed
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Sertifikat nr. 010 utstedt av Teknologisk Institutt viser godkjent overensstemmelse med styringssystemkravene i henhold til NS-EN-ISO 9001:2015, Ledelsessystemer for kvalitet, og NS-EN ISO 14001:2015, Ledelsessystemer for miljø.

Certificate No. 010 issued by the Norwegian 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.

Rognan/Bodø, 20.05.2021



Geir Tore Jakobsen
Administrerende direktør