

# Samsvarserklæring (Declaration of Conformity)

# HEPRO

Produsent (manufacturer)	Hepro AS
Organisasjonsnr.	937 162 103
Adresse (adress)	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.

Artic 17 (Artic 17)

Produktets risikoklasse: Klasse 1

Products risk class: Class 1

Tabell 1: Modeller (Table: 1 Models)

Art. nr	Product name	UDI-DI
29410	Arctic 17/40 Synkron S, stoff	07070419294102
29411	Arctic 17/40 Synkron H, hud	07070419294119
29412	Arctic 17/40 Synkron S Sving, stoff	07070419294126
29413	Arctic 17/40 Synkron H Sving, hud	07070419294133
29414	Arctic 17/45 Synkron S, stoff	07070419294140
29415	Arctic 17/45 Synkron H, hud	07070419294157
29416	Arctic 17/45 Synkron S Sving, stoff	07070419294164
29417	Arctic 17/45 Synkron H Sving, hud	07070419294171
29418	Arctic 17/50 Synkron S, stoff	07070419294188
29419	Arctic 17/50 Synkron H, hud	07070419294195
29420	Arctic 17/50 Synkron S Sving, stoff	07070419294201
29421	Arctic 17/50 Synkron H Sving, hud	07070419294218
29422	Arctic 17/55 Synkron S, stoff	07070419294225
29423	Arctic 17/55 Synkron H, hud	07070419294232
29424	Arctic 17/55 Synkron S Sving, stoff	07070419294249
29425	Arctic 17/55 Synkron H Sving, hud	07070419294256
29428	Arctic 17/60 Synkron S Sving	07070419294287
29429	Arctic 17/60 Synkron H Sving	07070419294297
29430	Arctic 17 Std. 40 u/sving, stoff	07070419294300

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29431	Arctic 17 Std. 40 u/sving, hud	07070419294324
29432	Arctic 17/40 Standard S Sving, stoff	07070419294331
29433	Arctic 17/40 Standard H Sving, hud	07070419294348
29434	Arctic 17 Std. 45 u/sving, stoff	07070419294348
29435	Arctic 17 Std. 45 u/sving, hud	07070419294355
29436	Arctic 17/45 Standard S Sving, stoff	07070419294362
29437	Arctic 17/45 Standard H Sving, hud	07070419294379
29438	Arctic 17 Std. 50 u/sving, stoff	07070419294386
29439	Arctic 17 Std. 50 u/sving, hud	07070419294393
29440	Arctic 17/50 Standard S Sving, stoff	07070419294409
29441	Arctic 17/50 Standard H Sving, hud	07070419294416
29442	Arctic 17 Std. 55 u/sving, stoff	07070419294423
29443	Arctic 17 Std. 55 u/sving, hud	07070419294430
29444	Arctic 17/55 Standard S Sving, stoff	07070419294447
29445	Arctic 17/55 Standard H Sving, hud	07070419294454
29446	Arctic 17/60 Standard S, stoff	07070419294461
29447	Arctic 17/60 Standard H, hud	07070419294478
29448	Arctic 17/60 Standard S Sving, stoff	07070419294485
29449	Arctic 17/60 Standard H Sving, hud	07070419294492
29450	Arctic 17/40 Tilt S, stoff	07070419294508
29451	Arctic 17/40 Tilt H, hud	07070419294515
29452	Arctic 17/40 Tilt S Sving, stoff	07070419294522
29453	Arctic 17/40 Tilt H Sving, hud	07070419294539
29454	Arctic 17/45 Tilt S, stoff	07070419294546
29455	Arctic 17/45 Tilt H, hud	07070419294553
29456	Arctic 17/45 Tilt S Sving, stoff	07070419294560
29457	Arctic 17/45 Tilt H Sving, hud	07070419294577
29458	Arctic 17/50 Tilt S, stoff	07070419294584
29459	Arctic 17/50 Tilt H, hud	07070419294591
29460	Arctic 17/50 Tilt S Sving, stoff	07070419294607
29461	Arctic 17/50 Tilt H Sving, hud	07070419294614
29462	Arctic 17/55 Tilt S, stoff	07070419294621
29463	Arctic 17/55 Tilt H, hud	07070419294638
29464	Arctic 17/55 Tilt S Sving, stoff	07070419294645
29465	Arctic 17/55 Tilt H Sving, hud	07070419294652
29466	Arctic 17/60 Tilt S, stoff	07070419294669
29467	Arctic 17/60 Tilt H, hud	07070419294676
29468	Arctic 17/60 Tilt S Sving, stoff	07070419294683
29469	Arctic 17/60 Tilt H Sving, hud	07070419294690

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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	Beskrivelse (Description)	Resultat (Result)
NS-EN 1021-1:2014	Furniture - Assessment of the ignitability of upholstered furniture - Part 1: Ignition source smouldering cigarette	Passed
NS-EN 1021-2:2014	Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source match flame equivalent	Passed
NS-EN 1022:2005	Domestic furniture - Seating - Determination of stability	Passed
NS-EN 16139:2013	Furniture - Strength, durability and safety - Requirements for non-domestic seating	Passed
ISO 17072-1:2011	Leather – Chemical determination of metal content- Part 1: Extractable metals	Passed
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.	Passed
ISO 10993-12:2012	Biological evaluation of medical devices Part 12: Sample preparation and reference materials.	Passed
NEK EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Passed

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NEK EN 60601-1:2006	Medical electrical equipment – Part1: General requirements for basic safety and essential performance	Passed
EN ISO 17075-1:2017	Leather – Chemical determination of chromium (VI) content in leather – Part1: Colorimetric method	Passed

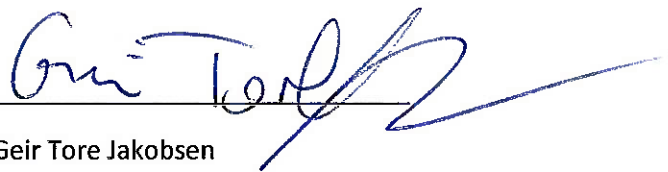
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Sertifikat nr. 010 utstedt av Teknologisk Institutt viser godkjent overensstemmelse med styringssystemkravene i henhold til NS-EN-ISO 9001:2015, Ledelsessystemer for kvalitet, og NS-EN ISO 14001:2015, Ledelsessystemer for miljø.

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, 19.05.2021



Geir Tore Jakobsen  
Administrerende direktør