

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000337968-PA-NA-NOR rev. 1.0

Project No.:
PRJC-500081-2014-PRC-NOR

Valid Until:
27 May 2024

This is to certify that the quality system of:

Minitech AS

Vikavegen 15B, 2312 Ottestad
Norway

For design, production and final product inspection/testing of:

Heating aids for disabled persons to be used to maintain normal body temperature when cold

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 01 April 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Sholeh Gheissar

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The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2020-01-09
1.0	Editorial change, product names are changed, and this certificate refers to full list of devices dated 16.03.2020	2020-04-01

Products covered by this Certificate:

Product Description	Product Name	Class
Heating aids for disabled persons	Minitech Varmehansker (Gloves)	IIb
	Minitech Varmevotter (Mitten)	
	Minitech Varmesokker/strømper (Socks)	
	Minitech Varmesåler (Insole)	
	Minitech Varmesko/støvel (Boots)	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Minitech AS	Vikavegen 15B, 2312 Ottestad, Norway
Minitech Sverige	Magasinsgatan 1B, 782 35 Malung, Sweden

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10000337968-PA-NA-NOR rev.1.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:

Minitech AS.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on the audit and assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A site has been relocated.

Site covered by certificate (replaces information on certificate)	
Site Name	Site Address
Minitech Sweden AB	Källvägen 17, 782 33 Malung, Sweden

A device already covered by the certification is placed on the market under an additional name or Identifier, as per list of devices dated: 03.12.2021.

Appendix History -		
Revision	Description	Issued Date
0.0	Change site and adding new models.	11 February 2022

Place and date:
Høvik, 11 February 2022



For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 3, 1363 Høvik, Norway


Palani Damodharan
Principal Assessor