

# 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*

**Sholeh Gheissar**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://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
<b>Heating aids for disabled persons</b>	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



**Notified Body Confirmation Letter Reference: C674820**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Minitech AS  
Todderudvegen 17  
2322 Ridabu  
Norway

SRN Number (if available): NO-MF-000008368

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:  
Høvik, 2024/04/03



For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway

**André Fernandes**  
Management Representative

# 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

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Valid Until:  
27 May 2024

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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 AS	Todderudvegen 17, 2322 Ridabu, Norway

Appendix History -		
Revision	Description	Issued Date
0.0	Change site and adding new models.	11 February 2022
1.0	Legal Manufacturer site has been relocated.	13 February 2024

Place and date:  
Høvik, 13 February 2024



For the issuing office:  
DNV Product Assurance AS - Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway



**Tone Elise Kolpus**  
Principle Auditor and Assessor