

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000510539-PA-NA-DNK

Initial certification date:
12 June 2022

Valid:
12 October 2022 – 12 June 2025

This is to certify that the management system of
OneMed Group Oy
Metsäläntie 20, 0320 Helsinki, Finland
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

The design, development and manufacturing of non-sterile and sterile non-active medical devices:

Sterile surgical gowns, sterile surgical drapes and sets, sterile instrument and equipment drapes, sterile fluid collection pouches, sterile tube holders, sterile x-ray detectable gauze swabs and sponges, sterile x-ray detectable nonwoven swabs and sponges;

Sterile irrigation sets, sterile intravenous infusion sets, sterile extension lines, sterile gravity sets, sterile IV-stopcocks, sterile monosets, sterile transfusion sets, sterile urology sets;

Sterile adhesive nonwoven dressings and sterile adhesive film dressings;

Sterile and non-sterile fixation bandages and support bandages, sterile and non-sterile gauze swabs and sponges, sterile and non-sterile nonwoven swabs and sponges, sterile and non-sterile absorbent dressings, sterile and non-sterile applicators for sampling and examination, sterile and non-sterile tapes;

Non-sterile examination gloves, non-sterile surgical masks, non-sterile surgical caps and hoods, non-sterile protective apparels, non-sterile blankets;

The design, development and manufacturing of active medical devices: Software applications for healthcare.

Place and date:
Høvik, 29 February 2024



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



DNV

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Appendix to Certificate

OneMed Group Oy

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
OneMed Group Oy	Metsäläntie 20, 0320 Helsinki, Finland	The design, development and manufacturing of non-sterile and sterile non-active medical devices: Sterile surgical gowns, sterile surgical drapes and sets, sterile instrument and equipment drapes, sterile fluid collection pouches, sterile tube holders, sterile x-ray detectable gauze swabs and sponges, sterile x-ray detectable nonwoven swabs and sponges; Sterile irrigation sets, sterile intravenous infusion sets, sterile extension lines, sterile gravity sets, sterile IV-stopcocks, sterile monosets, sterile transfusion sets, sterile urology sets; Sterile adhesive nonwoven dressings and sterile adhesive film dressings; Sterile and non-sterile fixation bandages and support bandages, sterile and non-sterile gauze swabs and sponges, sterile and non-sterile nonwoven swabs and sponges, sterile and non-sterile absorbent dressings, sterile and non-sterile applicators for sampling and examination, sterile and non-sterile tapes; Non-sterile examination gloves, non-sterile surgical masks, non-sterile surgical caps and hoods, non-sterile protective apparels, non-sterile blankets; The design, development and manufacturing of active medical devices: Software applications for healthcare.



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Site Name	Site Address	Site Scope
Evercare Medical AB	Tagenevägen 29, Box 50, SE-401 20, Göteborg, Sweden	The design, development and manufacturing of non-sterile and sterile non-active medical devices: Sterile surgical gowns, sterile surgical drapes and sets, sterile instrument and equipment drapes, sterile fluid collection pouches, sterile tube holders, sterile x-ray detectable gauze swabs and sponges, sterile x-ray detectable nonwoven swabs and sponges; Sterile irrigation sets, sterile intravenous infusion sets, sterile extension lines, sterile gravity sets, sterile IV-stopcocks, sterile monosets, sterile transfusion sets, sterile urology sets; Sterile adhesive nonwoven dressings and sterile adhesive film dressings; Sterile and non-sterile fixation bandages and support bandages, sterile and non-sterile gauze swabs and sponges, sterile and non-sterile nonwoven swabs and sponges, sterile and non-sterile absorbent dressings, sterile and non-sterile applicators for sampling and examination, sterile and non-sterile tapes; Non-sterile examination gloves, non-sterile surgical masks, non-sterile surgical caps and hoods, non-sterile protective apparels, non-sterile blankets; The design, development and manufacturing of active medical devices: Software applications for healthcare.

