

DECLARATION OF CONFORMITY

replaces version dated: 13.05.2015

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility that following products, all belonging to class I according to Annex IX of the Directive 93/42/EEC for medical devices,

Name, type or model:

2610	Standard scrub suit, shirt, size S
2611	Standard scrub suit, shirt, size M
2612	Standard scrub suit, shirt, size L
2613	Standard scrub suit, shirt, size XL
2614	Standard scrub suit, shirt, size XXL
2615	Standard scrub suit, pants, size XXL
2616	Standard scrub suit, pants, size S
2617	Standard scrub suit, pants, size M
2618	Standard scrub suit, pants, size L
2619	Standard scrub suit, pants, size XL
2620	Special scrub suit, shirt, size S
2621	Special scrub suit, shirt, size M
2622	Special scrub suit, shirt, size L
2623	Special scrub suit, shirt, size XL
2624	Special scrub suit, shirt, size XXL
2626	Special scrub suit, pants, size S
2627	Special scrub suit, pants, size M
2628	Special scrub suit, pants, size L
2629	Special scrub suit, pants, size XL
2630	Special scrub suit, pants, size XXL
2632	evercare® Essentia Scrub suit, shirt, size S
2633	evercare® Essentia Scrub suit, shirt, size M
2634	evercare® Essentia Scrub suit, shirt, size L
2635	evercare® Essentia Scrub suit, shirt, size XL
2636	evercare® Essentia Scrub suit, shirt, size XXL
2638	evercare® Essentia Scrub suit, pants, size S
2639	evercare® Essentia Scrub suit, pants, size M
2640	evercare® Essentia Scrub suit, pants, size L
2641	evercare® Essentia Scrub suit, pants, size XL
2642	evercare® Essentia Scrub suit, pants, size XXL
2660	evercare® Optimia Clean air suit, shirt, size XS
2661	evercare® Optimia Clean air suit, shirt, size S
2662	evercare® Optimia Clean air suit, shirt, size M
2663	evercare® Optimia Clean air suit, shirt, size L
2664	evercare® Optimia Clean air suit, shirt, size XL
2665	evercare® Optimia Clean air suit, shirt, size XXL
2666	evercare® Optimia Clean air suit, shirt, size XXXL
2667	evercare® Optimia Clean air suit, pants, size XS
2668	evercare® Optimia Clean air suit, pants, size S
2669	evercare® Optimia Clean air suit, pants, size M
2670	evercare® Optimia Clean air suit, pants, size L

- 2671 evercare® Optimia Clean air suit, pants, size XL
- 2672 evercare® Optimia Clean air suit, pants, size XXL
- 2673 evercare® Optimia Clean air suit, pants, size XXXL
- 2684 Warm-up jacket with medium sleeves, size S
- 2685 Warm-up jacket with medium sleeves, size M
- 2686 Warm-up jacket with medium sleeves, size L
- 2687 Warm-up jacket with medium sleeves, size XL
- 2690 Warm-up jacket, size S
- 2691 Warm-up jacket, size M
- 2692 Warm-up jacket, size L
- 2693 Warm-up jacket, size XL
- 2695 Warm-up jacket with short sleeves, size M
- 2696 Warm-up jacket with short sleeves, size L
- 2697 Warm-up jacket with short sleeves, size XL
- 260000 evercare® XP Warm-up jacket, short sleeves, size XS
- 260001 evercare® XP Warm-up jacket, short sleeves, size S
- 260002 evercare® XP Warm-up jacket, short sleeves, size M
- 260003 evercare® XP Warm-up jacket, short sleeves, size L
- 260004 evercare® XP Warm-up jacket, short sleeves, size XL
- 260005 evercare® XP Warm-up jacket, short sleeves, size XXL
- 260006 evercare® XP Warm-up jacket, short sleeves, size XXXL
- 260010 evercare® XP Warm-up jacket, medium sleeves, size XS
- 260011 evercare® XP Warm-up jacket, medium sleeves, size S
- 260012 evercare® XP Warm-up jacket, medium sleeves, size M
- 260013 evercare® XP Warm-up jacket, medium sleeves, size L
- 260014 evercare® XP Warm-up jacket, medium sleeves, size XL
- 260015 evercare® XP Warm-up jacket, medium sleeves, size XXL
- 260016 evercare® XP Warm-up jacket, medium sleeves, size XXXL
- 260020 evercare® XP Warm-up jacket, long sleeves, size XS
- 260021 evercare® XP Warm-up jacket, long sleeves, size S
- 260022 evercare® XP Warm-up jacket, long sleeves, size M
- 260023 evercare® XP Warm-up jacket, long sleeves, size L
- 260024 evercare® XP Warm-up jacket, long sleeves, size XL
- 260025 evercare® XP Warm-up jacket, long sleeves, size XXL
- 260026 evercare® XP Warm-up jacket, long sleeves, size XXXL
- 260100 evercare® XP Scrub Suit, Shirt, size XS
- 260101 evercare® XP Scrub Suit, Shirt, size S
- 260102 evercare® XP Scrub Suit, Shirt, size M
- 260103 evercare® XP Scrub Suit, Shirt, size L
- 260104 evercare® XP Scrub Suit, Shirt, size XL
- 260105 evercare® XP Scrub Suit, Shirt, size XXL
- 260106 evercare® XP Scrub Suit, Shirt, size XXXL
- 260200 evercare® XP Scrub Suit, Pants, size XS
- 260201 evercare® XP Scrub Suit, Pants, size S
- 260202 evercare® XP Scrub Suit, Pants, size M
- 260203 evercare® XP Scrub Suit, Pants, size L
- 260204 evercare® XP Scrub Suit, Pants, size XL
- 260205 evercare® XP Scrub Suit, Pants, size XXL
- 260206 evercare® XP Scrub Suit, Pants, size XXXL

to which this declaration relates, are in conformity with the following harmonized standards or other normative documents

EN ISO 13485:2012	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
EN ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

and with the provisions of the laws of Finland and with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of 5 September 2007.

Place and date of issue

Malmö 07.08.2017

Name and signature of the authorized person



Julien Rolland
Sourcing Director