ONEMED

DECLARATION OF CONFORMITY

replaces version dated: ---

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:

4531	**Absorbent dressing 10x10 cm, non-sterile**
4532	**Absorbent dressing 10x20 cm, non-sterile**
4533	**Absorbent dressing 10x30 cm, non-sterile**
4534	**Absorbent dressing 15x20 cm, non-sterile**
4535	**Absorbent dressing 15x25 cm, non-sterile**
4536	**Absorbent dressing 20x20 cm, non-sterile**
4537	**Absorbent dressing 20x25 cm, non-sterile**
4538	**Absorbent dressing 20x30 cm, non-sterile**
4539	**Absorbent dressing 20x40 cm, non-sterile**
4531-01	**evercare® HighClean Absorbent dressing 10x10 cm**
4532-01	**evercare® HighClean Absorbent dressing 10x20 cm**
4533-01	**evercare® HighClean Absorbent dressing 10x30 cm**
4534-01	**evercare® HighClean Absorbent dressing 15x20 cm**
4535-01	**evercare® HighClean Absorbent dressing 15x25 cm**
4536-01	**evercare® HighClean Absorbent dressing 20x20 cm**
4537-01	**evercare® HighClean Absorbent dressing 20x25 cm**
4538-01	**evercare® HighClean Absorbent dressing 20x30 cm**
4539-01	**evercare® HighClean Absorbent dressing 20x40 cm**
4541	**evercare® Absorbent dressing Extra 10x10 cm, non-sterile**
4542	**evercare® Absorbent dressing Extra 10x20 cm, non-sterile**
4545	**evercare® Absorbent dressing Extra 15x25 cm, non-sterile**
4546	**evercare® Absorbent dressing Extra 20x20 cm, non-sterile**
4549	**evercare® Absorbent dressing Extra 20x40 cm, non-sterile**

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.

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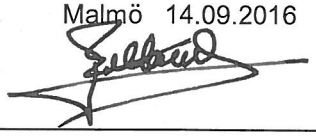
Place and date of issue

Malmö 14.09.2016

Name and signature of the authorized person



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