

**DECLARATION OF CONFORMITY**

replaces version dated: 22.05.2015

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:****210451 Face mask, 2-ply**

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	Graphical 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 26.06.2015

**Name and signature of the authorized person**

**Henrik Cederqvist**  
Product Area Director