ONEMED

DECLARATION OF CONFORMITY

replaces version dated: 27.05.2013

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

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

Name, type or model:

1810	**Tube cover 8x120 cm**
1815	**Tube cover 15x250 cm**
1820	**Tube cover, perforated tip, 15x240 cm**
1825	**Tube cover, elastic tip, 17x240 cm**
1830	**Tube cover, ring insert, 15x230 cm**

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

EN 13795:2011	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels
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
EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

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.

Identification of Notified Body (MDD): Det Norske Veritas, 0434.

Place and date of issue

Malmö 22.05.2015

Name and signature of the authorized person

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