

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

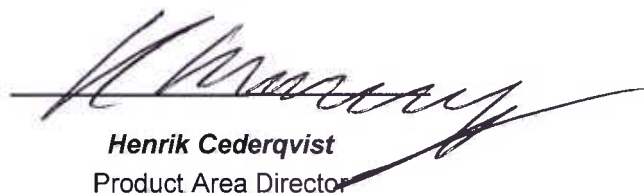
and with the provisions of the laws of Finland and with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of 5 September 2007.

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



Henrik Cederqvist
Product Area Director