DECLARATION OF CONFORMITY

Replace version from 10.04.2017

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

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

Name, type or model:

1320113502	**Batist®Adhesive surgical dressing with pad 5x7 cm, Elastpore+pad, sterile**
1320113503	**Batist®Adhesive IV dressing with pad 6x8 cm, Elastpore+pad IV, sterile**
1320113504	**Batist®Adhesive surgical dressing with pad 10x10 cm, Elastpore+pad, sterile**
1320113505	**Batist®Adhesive surgical dressing with pad 10x15 cm, Elastpore+pad, sterile**
1320113506	**Batist®Adhesive surgical dressing with pad 10x20 cm, Elastpore+pad, sterile**
1320113507	**Batist®Adhesive surgical dressing with pad 10x25 cm, Elastpore+pad, sterile**
1320113508	**Batist®Adhesive surgical dressing with pad 10x30 cm, Elastpore+pad, 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 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 11135:2014	Sterilization of health care products – Ethylene oxide -Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2009 + A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006+ A1:2014	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 21.04.2017

Name and signature of the authorized person

Julien Rolland
Sourcing Director

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