

DECLARATION OF CONFORMITY

replaces version dated: 17.03.2017

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:

1001	Universal set
1003	Essentia Universal set
1005-01, 1005-02	Universal set w. Mayo stand cover
1006-01	Universal set w. Mayo stand cover
1007	Universal set
1010-01, 1010-02	Universal set w. Mayo stand cover
1011-01, 1011-02	Universal set w. Mayo stand cover, abs. patch 25x60 cm
1014-01, 1014-02	Universal set w. Mayo stand cover and fluid collection pouch
1015-01, 1015-02	Universal set without Mayo stand cover
1020-01	Universal set w. extra drape sheet
1025-01	Universal set w. 2 surgeon's gowns
1030-01, 1030-02	Paediatric universal set
1050-01, 1050-02, 1050-50	Split sheet set
1051-01, 1051-02	Split sheet set
1205-01	Hip set
1210-01, 1210-02	Hip set Standard
1215-01, 1215-02	Hip set Large
1220-01, 1220-02	Hip set Special
1225-01, 1225-02	Vertical drape set, small
1226-01, 1226-02	Vertical drape set, large
1230-01, 1230-02	Extremity set
1231-01, 1231-02, 1231-100	Extremity set
1232-01, 1232-02, 1232-50	Hand/foot set
1233-01, 1233-02	Extremity set
1234-01	Extremity set bilateral
1235-01, 1235-02, 1235-50	Knee arthroscopy set
1236	Shoulder split sheet set with pouch
1246	Aorta set
1248-50	Abdominal-perineal set
1250-01, 1250-50	Gynae/Cyst set
1251-01, 1251-02	Gynaecology set
1252	Gynaecology and urology set
1253-01	Gynaecology set
1255-01	Delivery set
1260-01, 1260-02	C-section set, incision film with hole
1261-01, 1261-02	C-section set, incision film
1262	C-section set, incision film
1267-01, 1267-02	Laparoscopy set
1288-01	Dental set
1290-01, 1290-02	Dental set
1291-01, 1291-02	Head/neck drape

1292	Craniotomy set
1307	Adhesive split sheet 120x180 cm, split 15x50 cm, transparent
1308	Adhesive split sheet 150x183 cm, split 7x70 cm
1309	Adhesive split sheet, bilateral 230x290 cm, splits 6x90 cm
1310-01, 1310-02	Adhesive split sheet 150x250 cm, split 7x70 cm
1315-01	Adhesive split sheet 230x260 cm, split 20x100 cm
1316-01	Adhesive split sheet 230x260 cm, split 20x100 cm
1317-01	Lower vascular drape, 230x260 cm, split 20x100 cm, integrated genital cover
1318-01	Adhesive split sheet 200x260 cm, split 7x100 cm
1319	Beach chair shoulder drape 400 x 230 cm, with pouch
1320-01	Hand/foot drape 150x180 cm, aperture 3,5 cm
1324-01, 1324-02	Hand/foot drape 230x300 cm, aperture 3,5 cm
1325-01	Extremity drape 230x300 cm, aperture 7 cm
1328	Knee arthroscopy drape 230x320 cm
1330-01, 1330-02	Vertical drape, small
1332-01, 1332-02	Vertical drape, large
1355	Gyn-abdominal drape 220/240x335 cm
1356-01	Perineal drape
1365-01	Laparoscopy drape 230x300 cm, aperture 25x20 cm, triangle
1366-01	Laparoscopy drape 230x300 cm, aperture 20x31 cm
1375-01	Thoracic drape 200/300x330 cm, aperture 32x40 cm
1398-01	Arm cover
1408	Utility drape 45x75 cm
1410-01	Utility drape 50x60 cm
1415-01	Utility drape 75x90 cm
1418	Universal cover drape 150x240 cm, extra reinforced
1451-01	Adhesive drape sheet 45x75 cm
1452-01	Adhesive drape sheet 50x50 cm
1453-01	Adhesive drape sheet 100x100 cm
1454-01	Adhesive drape sheet 75x100 cm
1455-01	Adhesive drape sheet 50x60 cm
1456-01	Adhesive drape sheet 37x45 cm
1460-01, 1460-02	Adhesive drape sheet 75x90 cm
1461-01	Adhesive drape sheet 75x75 cm
1463-01, 1463-02	Absorbent drape 70x60 cm
1463-50	Paediatric adhesive absorbent drape 70x60 cm
1464	Adhesive drape Large 254x180cm
1465-01, 1465-02	Adhesive drape Medium 180x180 cm
1466	Adhesive drape 150x170 cm
1470-01, 1470-02	Adhesive drape Large 150x240 cm
1505-01	Adhesive aperture drape 50x60 cm, aperture 6x8 cm
1510-01	Epidural drape 75x80 cm, aperture 6x15 cm
1511	Paediatric adhesive aperture drapes variable 37x65 cm
1512-01	Adhesive aperture drapes variable 50x75 cm
1513-01	Adhesive aperture drapes variable 75x100 cm
1515-01	Adhesive aperture drape 75x90 cm, aperture 6x8 cm
1516	Adhesive aperture drape, transparent 80x130 cm, aperture 15x6 cm
1517	Adhesive aperture drape 100x125 cm, aperture 11 cm
1520-01	Adhesive aperture drape 120x150 cm, aperture 5x7 cm
1525-01	Adhesive aperture drape 120x150 cm, aperture 5x7 cm
1530-01	Adhesive aperture drape 150x180 cm, aperture 6x15 cm
1535-01, 1535-02	Adhesive aperture drape 230x250 cm, aperture 12 cm
1537-01	Adhesive aperture drape 200 x 280 cm, aperture 14x14 cm

1538-01	Adhesive aperture drape 200 x 240 cm, aperture 12 cm
1539-01	Adhesive aperture drape 200 x 280 cm, aperture 15 cm
1555-01	Aperture drape, 50x60 cm, aperture 6x8 cm
1565-01	Aperture drape, 75x90 cm, aperture 6x8 cm
1741-01	Under buttock drape 75x100 cm

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

EN 13795:2011 + A1:2013	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 11135:2014	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 12.06.2017

Name and signature of the authorized person



Julien Rolland
Sourcing Director