

# Product Data Sheet

Drapes and sets



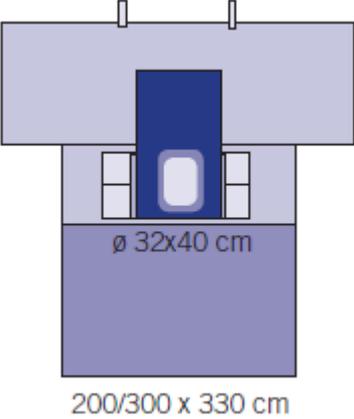
**REF 1375-01**

**Thoracic drape 200/300 x 330 cm**

Page 1 (2)

Version: 25.10.2017, rev. 2

Last modified: 7.11.2017

<p>CE2460 The product complies with legal requirements for medical devices EO sterilized according to valid version of ISO 11135 standard <b>[ NATURAL LATEX FREE ]</b></p>	
<p><b>Contents</b> 1375-01 thoracic drape 200/300 x 330 cm, aperture 32 x 40 cm with incision film, fluid collection pouches, absorbent patch 50 x 150cm, tube holders</p>	<p><b>Raw material</b> Laminate: blue PP nonwoven/blue PE-film, absorbent patch blue PP nonwoven Fluid collection pouches transparent LPDE/LLPDE/EPA film Incision film PUR Coated metallic wire in fluid collection pouches</p>
<p><b>REACH regulations:</b></p>	<p>The product covered by this data sheet specification does not contain carcinogenic, mutagenic or toxic substances, including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).</p>
<p><b>Features:</b></p>	<p>Tear-resistant and fluid-proof thoracic drape with incision film for cardiovascular procedures. Absorbent patch reinforcement for fluid management. Secure attachment for tubing with tube holders</p>
<p><b>Shelf life:</b></p>	<p>5 years</p>
<p><b>Pack count:</b></p>	<p>1 pc/unit pack, 7 pcs/dispenser, 14 pcs/transport carton</p>
<p><b>Sales unit:</b></p>	<p>Transport carton</p>
<p><b>Unit pack:</b></p>	<p>Tyvek/polyethylene/polyester film pouch 420 x 603 mm</p>
<p><b>Dispenser box</b></p>	<p>Cardboard, totally chlorine free, size 285 x 287 x 485 mm</p>
<p><b>Transport carton:</b></p>	<p>Cardboard, totally chlorine free, size 300 x 590 x 500 mm</p>
<p><b>Packing tape:</b></p>	<p>Transparent, PVC-free</p>
<p><b>Compliance with legal requirements:</b></p>	<p>Medical Devices Directive 93/42/EEC, Class Is</p>
<p><b>Compliance with product standards:</b></p>	<p>EN13795</p>
<p><b>Quality standards:</b></p>	<p>The product is manufactured in compliance with, EN ISO 13485</p>
<p><b>Label information:</b></p>	<p>in accordance with EN ISO 15223-1, EN 980 and EN1041</p>
<p><b>Storage recommendation:</b></p>	<p>Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone</p>
<p><b>Disposal recommendation</b></p>	<p>Follow local instructions.</p>
<p><b>Risk if reused:</b></p>	<p>The product is single use. If reused performance of product may deteriorate, cross contamination may occur</p>

# Product Data Sheet

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**REF 1375-01**

**Thoracic drape 200/300 x 330 cm**

Page 2 (2)

Version: 25.10.2017, rev. 2

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Barcodes: Unit pack	Dispenser	Transport carton
6438129110524 1375 single  6 438129 110524	6438129310528 1375 dispenser  6 438129 310528	6438129510522 1375 carton  6 438129 510522

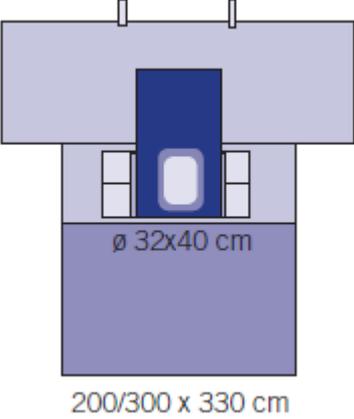
**REF 1375-01**

**Torakalinės dalies apklotas**

**200/300 x 330 cm**

Puslapis 1 (2)

Versija: 25.10.2017, rev. 2

<p>CE2460                  Produktas atitinka teisinius reikalavimus medicinos prietaisams                  EO sterilizuotas pagal galiojančią ISO 11135 standarto versiją</p> <p><b>[ NATURAL LATEX FREE ]</b>                  BE LATEKSO</p>	
<p><b>Sudėtis</b>                  1375-01 torakalinės dalies apklotas 200/300 x 330 cm, anga 32 x 40 cm su incizine plėvele, skysčių surinkimo maišeliais, absorbuojančios dalies dydis 50 x 150 cm, su vamzdelių laikikliais</p>	<p><b>Medžiaga</b>                  Laminuota: mėlyna PP neaustinė medž./mėlynas PE-filmas, mėlyna neaustinės medžiagos absorbuojanti dalis                  Skysčių surinkimo maišeliai yra skaidrios LDPE / LLDPE / EPA plėvelės, Incizinė plėvelė                  Dengta metalinė viela skysčių surinkimo maišeliuose</p>
<p><b>REACH reguliavimas:</b></p>	<p>Produkte, kuriam taikoma ši duomenų lapo specifikacija, nėra kancerogeninių, mutageninių ar toksiškų medžiagų, įskaitant nė vienas iš labai didelį susirūpinimą keliančių medžiagų (SVHC), išvardytų naujausioje Europos cheminių medžiagų agentūros (ECHA) paskelbto kandidatų sąrašo versijoje.</p>
<p><b>Privalumai:</b></p>	<p>Lašams ir skysčiams atsparus krūtinės ląstos apklotas su įpjovimo plėvele širdies ir kraujagyslių procedūroms atlikti. Absorbuojanti dalis skirta gausių išskirų sugerimui. Vamzdelių laikikliai</p>
<p><b>Galiojimas:</b></p>	<p>5 metai</p>
<p>Pakuočių skaičius:</p>	<p>1 vnt / vienetinė pakuotė, 7 vnt / dozatorius, 14 vnt / transportavimo dėžutė</p>
<p>a</p>	<p>Transporto dėžutė</p>
<p>Vienetinė pakuotė:</p>	<p>Tyvek / polietileno / poliesterio plėvelės maišelis 420 x 603 mm</p>
<p>Dozavimo dėžutė</p>	<p>Kartonas, visiškai be chloro, dydis 285 x 287 x 485 mm</p>
<p>Transporto dėžutė:</p>	<p>Kartonas, visiškai be chloro, dydis 300 x 590 x 500 mm</p>
<p>Pakavimo juosta:</p>	<p>Skaidrus, be PVC</p>
<p>Teisinių reikalavimų laikymasis:</p>	<p>Medicinos prietaisų direktyvos 93/42 / EEB I s klasė</p>
<p>Produktų standartų laikymasis:</p>	<p>EN13795</p>
<p>Kokybės standartai:</p>	<p>Produktas pagamintas laikantis EN ISO 13485</p>
<p>Informacija etiketėje:</p>	<p>pagal EN ISO 15223-1, EN 980 ir EN1041</p>
<p>Sandėliavimo rekomendacija:</p>	<p>Rekomenduojama laikyti švarioje, sausoje vietoje, aplinkos temperatūroje. Produktai turi būti apsaugoti nuo tiesioginių saulės spindulių, kitų intensyvių šviesos šaltinių ir ozono</p>
<p>Šalinimo rekomendacija</p>	<p>Vykdykite vietines instrukcijas.</p>
<p>Pavojus pakartotinai naudojant:</p>	<p>Produktas yra vienkartinis. Jei pakartotinis produkto veikimas gali pablogėti, gali atsirasti kryžminis užteršimas</p>

# Produkto duomenų lapas

Apklotai ir rinkiniai



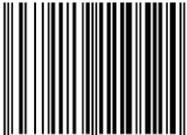
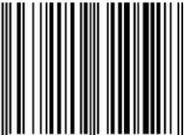
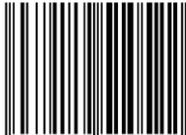
**REF 1375-01**

**Torakalinės dalies apklotas**

**200/300 x 330 cm**

Puslapis 2 (2)

Versija: 25.10.2017, rev. 2

Barcodes: Unit pack	Dispenser	Transport carton
6438129110524 1375 single  6 438129 110524	6438129310528 1375 dispenser  6 438129 310528	6438129510522 1375 carton  6 438129 510522

# Apsauga Komfortas Praktiškumas

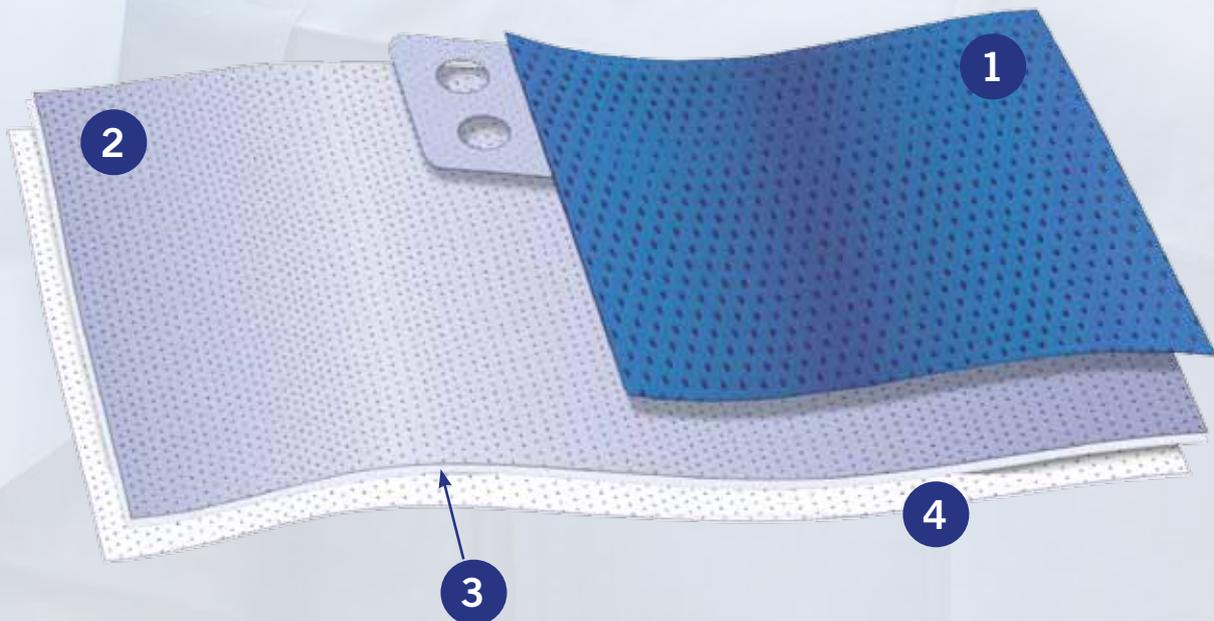
- Labai patvarūs-neperšlampantys
- Puikus sugeriamumas - padidintos skysčius sugeriančių apklotų dalys
- Labai mažai besielektrinantys (nedulka, nesipūkuoja)
- Labai lankstūs, puikiai priglundantys
- Neslidūs, lieka savo vietoje
- Mažesnė refleksija
- Aukšto lygio atsparumas dūriams-labai tvirti
- Lipnios dalys nepalieka klijų žymių ant odos

**1** Padidintos, labai efektyviai skysčius sugeriančių apklotų dalys, nauja struktūra

**2** Nauja žydra/žalsva neaustinė medžiaga, labai mažai besielektrinti (nedulka, nesipūkuoja)

**3** Nepaprastai elastinga daugiakomponentė drėgmės barjero plėvelė-užtikrina atsparumą dūriams

**4** Apatinis baltos spalvos sluoksnis su labai žemu dalelių praradimo lygiu, didesnis komfortas pacientui, daugiau tvirtumo.



# Turinys

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Apklotuose su skysčius sugeriančiomis dalimis integruoti gerai matomi vamzdelių laikikliai

## Medžiagų žymėjimas

	Absorbuojanti ir nepralaidi daugiasluoksnė medžiaga
	Absorbuojanti ir nepralaidi 2 sluoksnių medžiaga
	Absorbuojanti padidintos apsaugos nepralaidi medžiaga
	Polietileno plėvelė
	Elastinga medžiaga
	Lipnus kraštas/lipni dalis



# Specialūs apklotai

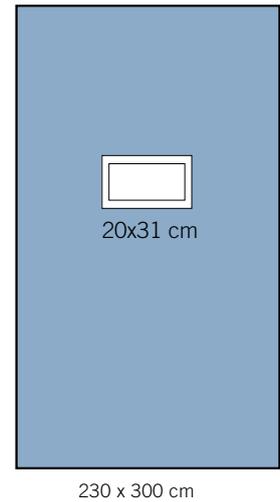
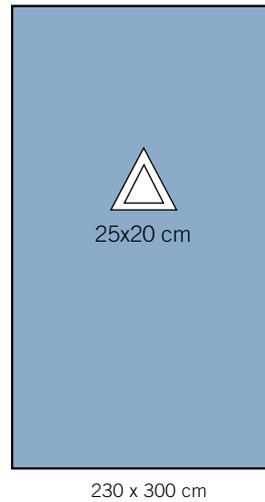
## Laparoskopinis apklotas

### REF 1365-01

- 230 x 300 cm su trikampio formos 20 x 25 cm anga
- Supakuota: 1/9/18

### REF 1366-01

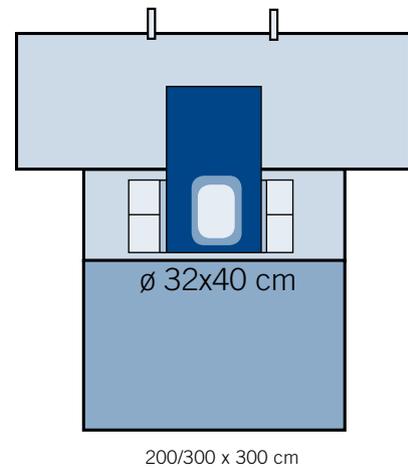
- 230 x 300 cm su stačiakampio formos 20 x 31 cm anga
- Supakuota: 1/9/18



## Torakalinės dalies apklotas

### REF 1375-01

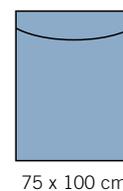
- 220/300 x 330 cm su skysčių surinkimo maišu, 32 x 40 cm anga ir operacinio lauko plėvele
- Supakuota: 1/7/14



## Apklotas po sėdmenimis

### REF 1741-01

- 75 x 100 cm
- Supakuotas: 1/25/100



# Informacija ant etikečių atitinka EN980 ir EN1041 reikalavimus

OneMed yra registruotas kompanijos OneMed Oy skiriamasis ženklas

Gaminio numeris

Dydis

Partijos kodas

Galioja iki

Sterilizavimo metodas  
- jonizuojanti spinduliuotė R  
- etileno oksidas EO

Vienkartinio naudojimo

CE ženklas  
Patvirtina, kad produktas atitinka Europos medicinos prietaisų reikalavimus

ir notifikuotos sertifikavimo įstaigos indentifikavimo numeris

Atsekamumo užtikrinimui visi produktai turi klijuojamą etiketę su brūkšniu kodu

Sudėtyje nėra latekso

Gamintojo kontaktinė informacija

## DECLARATION OF CONFORMITY

Replaces version dated:  
**19.01.2023.**

Valid until the issue of next  
version of this document.

We,

**OneMed Group Oy,**  
Metsäläntie 20,  
FI-00320 Helsinki, Finland,

SRN FI-MF-000000642,

Domicile Helsinki,  
Business ID 2039640-1,

declare under our sole responsibility that following products are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and its corrigenda on May 2019 and on December 2019.

### Classification:

**Class I (sterile)** according to Annex VIII of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

### Intended Purpose:

**Surgical drapes, general-purpose, sterile** are single-use sterile drape, or a collection of various drapes packed together into a ready-made set, designed to isolate a site of surgical incision or surgical / procedure field from microbial and particulate contamination in an operating or procedure room.

Intended Users are Health Care Professionals.

There is no restriction to a specific patient population.

The product is sterile.

The product intended for single use.

Duration of product use is short term contact (no more than 30 days).

The products principle of operation is to function as a mechanical barrier covering the parts of the patient's body, preventing transfer of airborne organisms into the surgical wound.

The evercare<sup>®</sup> drapes are assessed to be High Performance drapes according the standard EN 13795-1. The Critical area of a High-Performance drape is the whole drape area, surrounding the surgical incision site. While Less Critical area of a High-Performance drape area is on side drapes used for covering non-surgical site.

List of devices under Basic UDI-DI 6438129B0049HQ

Item number (REF)	Product name
1001	evercare <sup>®</sup> Universal set
1003	evercare <sup>®</sup> Essentia Universal set
1005-02	evercare <sup>®</sup> Universal set with Mayo stand cover, 2-layer, without abs. patches
1006-01	evercare <sup>®</sup> Universal set with Mayo stand cover, 2-layer, 15x50 cm abs. patches
1010-02	evercare <sup>®</sup> Universal set with Mayo stand cover, 3-layer, 85 cm tapes
1011-02	evercare <sup>®</sup> Universal set with Mayo stand cover, 3-layer, abs. patch 25 x 60 cm
1015-02	evercare <sup>®</sup> Universal set without Mayo stand cover, 3-layer, 25x60 cm patches
1030-02	evercare <sup>®</sup> Paediatric universal set
1050-02	evercare <sup>®</sup> Split sheet set
1050-50	evercare <sup>®</sup> Split sheet set
1051-02	evercare <sup>®</sup> Split sheet set
1205-01	evercare <sup>®</sup> Hip set
1210-02	evercare <sup>®</sup> Hip set Standard
1230-02	evercare <sup>®</sup> Extremity set
1231-02	evercare <sup>®</sup> Extremity set
1231-100	evercare <sup>®</sup> Extremity set
1232-02	evercare <sup>®</sup> Hand/foot set
1232-50	evercare <sup>®</sup> Hand/foot set
1235-02	evercare <sup>®</sup> Knee arthroscopy set
1235-50	evercare <sup>®</sup> Knee arthroscopy set
1236	evercare <sup>®</sup> Shoulder split sheet set with pouch
1238-03	evercare <sup>®</sup> ENT set
1239-01	evercare <sup>®</sup> Angiography set
1240-02	evercare <sup>®</sup> Angiography set
1241-02	evercare <sup>®</sup> Angiography set
1248-50	evercare <sup>®</sup> Abdominal-perineal set
1250-01	evercare <sup>®</sup> Gynae/cyst set
1251-02	evercare <sup>®</sup> Gynaecology set
1252	evercare <sup>®</sup> Gynaecology and urology set
1253-01	evercare <sup>®</sup> Gynaecology set
1255-01	evercare <sup>®</sup> Delivery set
1267-02	evercare <sup>®</sup> Laparoscopy set
1270-02	evercare <sup>®</sup> TUR set
1272-01	evercare <sup>®</sup> TUR set
1282-01	evercare <sup>®</sup> Ophthalmic set, 2 fluid collection pouches
1288-01	evercare <sup>®</sup> Dental set
1290-02	evercare <sup>®</sup> Dental set
1291-02	evercare <sup>®</sup> Head/neck drape
1308	evercare <sup>®</sup> Adhesive split sheet, 150 x 183 cm, split 7 x 70 cm
1309	evercare <sup>®</sup> Adhesive split sheet, bilateral, 230 x 290 cm, splits 6 x 90 cm
1310-02	evercare <sup>®</sup> Adhesive split sheet 150 x 250 cm, split 7 x 70 cm
1315-01	evercare <sup>®</sup> Adhesive split sheet 230 x 260 cm, split 20 x 100 cm
1316-01	evercare <sup>®</sup> Adhesive split sheet 230 x 260 cm, split 20 x 100 cm
1317-01	evercare <sup>®</sup> Lower vascular drape 230 x 260 cm, split 20 x 100 cm, integrated genital cover

1318-01	evercare <sup>®</sup> Adhesive split sheet 200 x 260 cm, split 7 x 100 cm
1320-01	evercare <sup>®</sup> Hand/foot drape 150 x 180 cm, aperture 3,5 cm
1324-02	evercare <sup>®</sup> Hand/foot drape 230 x 300 cm, aperture 3,5 cm
1325-01	evercare <sup>®</sup> Extremity drape 230 x 300 cm, aperture 7 cm
1328	evercare <sup>®</sup> Knee arthroscopy drape, 230 x 320 cm
1340-01	evercare <sup>®</sup> Angiography drape 230 x 300 cm
1356-01	evercare <sup>®</sup> Perineal drape
1365-01	evercare <sup>®</sup> Laparoscopy drape 230 x 300 cm, aperture 25 x 20 cm, triangle
1366-01	evercare <sup>®</sup> Laparoscopy drape 230 x 300 cm, aperture 25 x 31 cm
1390-01	evercare <sup>®</sup> Leggings, 75 x 120 cm, 2 pcs
1398-01	evercare <sup>®</sup> Arm cover
1410-01	evercare <sup>®</sup> Utility drape 50 x 60 cm
1415-01	evercare <sup>®</sup> Utility drape 75 x 90 cm
1418	evercare <sup>®</sup> Universal cover drape 150 x 240 cm, extra reinforced
1451-01	evercare <sup>®</sup> Adhesive drape sheet, 45 x 75 cm
1452-01	evercare <sup>®</sup> Adhesive drape sheet, 50 x 50 cm
1453-01	evercare <sup>®</sup> Adhesive drape sheet 100 x 100 cm
1454-01	evercare <sup>®</sup> Adhesive drape sheet, 75 x 100 cm
1455-01	evercare <sup>®</sup> Adhesive drape sheet 50 x 60 cm
1460-02	evercare <sup>®</sup> Adhesive drape sheet 75 x 90 cm
1461-01	evercare <sup>®</sup> Adhesive drape sheet 75 x 75 cm
1463-02	evercare <sup>®</sup> Absorbent drape 70 x 60 cm
1463-50	evercare <sup>®</sup> Paediatric absorbent drape, 70 x 60 cm
1465-02	evercare <sup>®</sup> Adhesive drape sheet Medium 180 x 180 cm
1466	evercare <sup>®</sup> Adhesive drape sheet, 150 x 175 cm
1470-02	evercare <sup>®</sup> Adhesive drape sheet Large, 150 x 240 cm
1494	evercare <sup>®</sup> Adhesive Impermeable OP Tape, 9 x 50cm
1505-01	evercare <sup>®</sup> Adhesive aperture drape 50 x 60 cm, aperture 6 x 8 cm
1510-01	evercare <sup>®</sup> Epidural drape 75 x 80 cm, aperture 6 x 15 cm
1511	evercare <sup>®</sup> Paediatric adhesive aperture drape, 35 x 65 cm, variable aperture
1512-01	evercare <sup>®</sup> Adhesive aperture drape, variable, 50 x 75 cm
1513-01	evercare <sup>®</sup> Adhesive aperture drape, variable, 75 x 100 cm
1515-01	evercare <sup>®</sup> Adhesive aperture drape 75 x 90 cm, aperture 6 x 8 cm
1516	evercare <sup>®</sup> Adhesive aperture drape, transparent, 80 x 130 cm
1517	evercare <sup>®</sup> Adhesive aperture drape, 100 x 125 cm, aperture 11 cm
1520-01	evercare <sup>®</sup> Adhesive aperture drape 120 x 150 cm, aperture 5 x 7 cm
1525-01	evercare <sup>®</sup> Adhesive aperture drape 150 x 180 cm, aperture 5 x 7 cm
1530-01	evercare <sup>®</sup> Adhesive aperture drape 150 x 180 cm, aperture 6 x 15 cm
1535-02	evercare <sup>®</sup> Adhesive aperture drape 230 x 250 cm, aperture 12 cm
1537-01	evercare <sup>®</sup> Adhesive aperture drape, 200 x 280 cm, aperture 14 x 14 cm
1538-01	evercare <sup>®</sup> Adhesive aperture drape, 200 x 240 cm, aperture 12 cm
1539-01	evercare <sup>®</sup> Adhesive aperture drape, 200 x 280 cm, aperture 15 cm
1555-01	evercare <sup>®</sup> Aperture drape 50 x 60 cm, aperture 6 x 8 cm
1565-01	evercare <sup>®</sup> Aperture drape 75 x 90 cm, aperture 6 x 8 cm
1741-01	evercare <sup>®</sup> Under buttock drape 75 x 100 cm
1878	evercare <sup>®</sup> Dislocation bag, 120 x 75 cm

**List of devices under Basic UDI-DI 6438129B0048HN:**

<b>Item number (REF)</b>	<b>Product name</b>
1225-02	evercare <sup>®</sup> Vertical drape set Small
1226-02	evercare <sup>®</sup> Vertical drape set Large
1261-02	evercare <sup>®</sup> C-section set, incision film
1280-01	evercare <sup>®</sup> Ophthalmic set, incision film
1330-02	evercare <sup>®</sup> Vertical drape Small
1332-02	evercare <sup>®</sup> Vertical drape Large
1375-01	evercare <sup>®</sup> Thoracic drape 200/300 x 330 cm, aperture 32 x 40 cm

**These items are in conformity with following European standards and common specifications<sup>1</sup>:**

EN ISO 13485	Medical Devices – Quality management systems requirements for regulatory purposes
EN ISO 14971	Medical Devices – Application of risk management
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels – Part 1: General requirements
EN ISO 20417	Medical Devices - Information to be supplied by the manufacturer
EN 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management
EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Irritation and hypersensitivity
EN 556-1	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11138-2	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 14644-1	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
EN ISO 11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN 13795-1	Surgical clothing and drapes. Requirements and test methods. Part 1: Surgical drapes and gowns

<sup>1</sup>Latest applied revisions of regulations, standards and common specifications are presented in *T-079 Review of regulations and standards*

**Conformity assessment procedure:**

Chapter I of Annex IX of the Regulation (EU) 2017/745.

**EU Quality Management Certificate number** 10000510540-PA-NoMA-DNK

**EU Quality Management Certificate validity** 18.05.2027

**Notified Body:**

DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, identification number 2460.

**Place and date of issue**

Helsinki, 30.11.2023

**Name and signature of the authorized person**



Hilleriikka Vaho  
**Regulatory Manager**  
OneMed Group Oy