Product Data Sheet

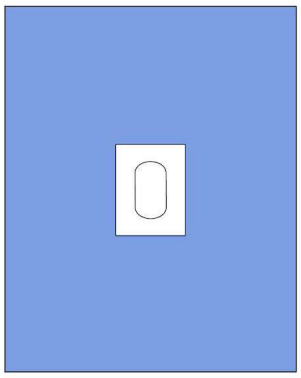
evercare® Adhesive aperture drape 75 x 90 cm, aperture 6 x 8 cm

REF: 1515-01

evercare® Adhesive aperture drape, sterile with adhesive aperture provides easy and quick draping for a variety of procedures.

Key Features

- Easy and quick draping
- Complies to EN 13795-1 High performance critical product area requirements



75 x 90 cm
ø 6 x 8 cm

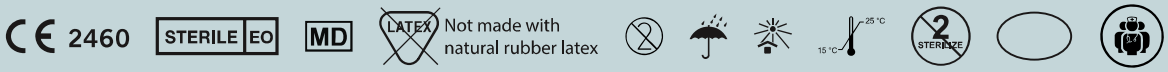
REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
1515-01	Adhesive aperture drape, sterile, Blue	75 x 90 cm, Ø 6 x 8 cm	25 / 100

Sales Unit: Transport Carton

Technical Summary

Regulations

The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.



REACH regulation:	The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), 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).
Biological evaluation:	EN ISO 10993-01 EN ISO 10993-5 EN ISO 10993-7 EN ISO 10993-10
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class Is
Compliance with product standards:	EN13795-1
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1

Material

Product Part	Raw Material & Characteristics
Laminate	PP nonwoven, blue / PE-film, blue

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. Do not use if package is damaged
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
Disposal Recommendation	Dispose in accordance with local regulations.
Shelf Life	5 Years

Packing information

Package	Material	Size (L x W x H) mm
Single Pack	Medical grade paper, Transparent	150 x 290
Dispenser Pack	TCF or ECF quality	265 x 143 x 234
Transport Carton	TCF or ECF quality	545 x 310 x 246
Packing Tape	Transparent	N/A

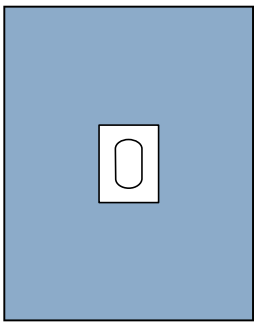
Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
1515-01	06438129110647	06438129310641	06438129510645

Evercare Medical AB is a partner that enables better lives for patients, facilitates everyday life for healthcare employees and contributes to lower care costs. We strive to reduce the environmental impact and, together with our suppliers, to improve working conditions throughout the value chain.

Apklotas su lipnia anga

REF 1515-01
75 x 90 cm
Ø 6 x 8 cm
Supakuota: 1/25/100



75 x 90 cm
ø 6 x 8 cm

COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 13485

evercare® medical

DECLARATION OF CONFORMITY

Replaces version dated:
15.07.2022
Valid until the issue of next version of this document.

We,

OneMed Group Oy, **SRN** FI-MF-000000642, Domicile Helsinki,
Metsäläntie 20, Business ID 2039640-1,
FI-00320 Helsinki, Finland,

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® 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

1515-01	evercare® Adhesive aperture drape 75 x 90 cm, aperture 6 x 8 cm

[1]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 3, 1363 Høvik, Norway, identification number 2460.

Place and date of issue Helsinki, 19.01.2023

Name and signature of the authorized person

Regulatory Manager
OneMed Group Oy

OneMed

evercare®

Produktų katalogas

Chirurginiai apklotai & rinkiniai

2017

evercare®

Surgical Drapes & Sets

Infection Control

evercare® drapes are designed for patient safety to provide an impermeable barrier against microbial penetration. Saugus pacientams užtikrina pilna barierą mikrobų prasiskverbimui

evercare® drapes provide effective fluid control across the entire surface and have highly absorbent reinforcements placed where most needed.

The drape material has been developed to ensure minimal particle release (low linting).

User Friendliness

evercare® drapes are easy to unfold and conform to the patient's body contours.

The low reflection of the drape material will not disturb the operating theatre personnel in what is otherwise a stressful environment (the blue/grey color is easy on the eyes).

The soft inner lining of evercare® drapes provides patient comfort and also prevents slipping.

The specially designed adhesive edges are easy to open up even if they adhere to each other due to a draping failure. With evercare® adhesive edges there is no chance that gloves will get stuck to the adhesive.

The adhesives used are known for their skin friendliness: there will be no damage to the skin when the drapes are removed from the patient post-surgery.

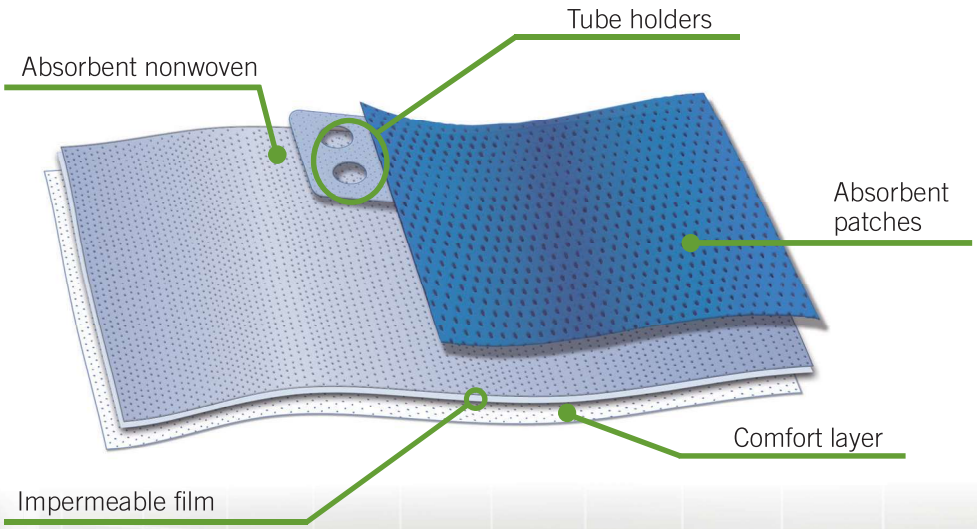
Cost Effectiveness

The development of evercare® drapes was driven by innovation.

The material is based on the latest polymer technology and is very cost effective.

Designs contain many unique features that help to reduce the set-up time and also provide extra support during surgery.

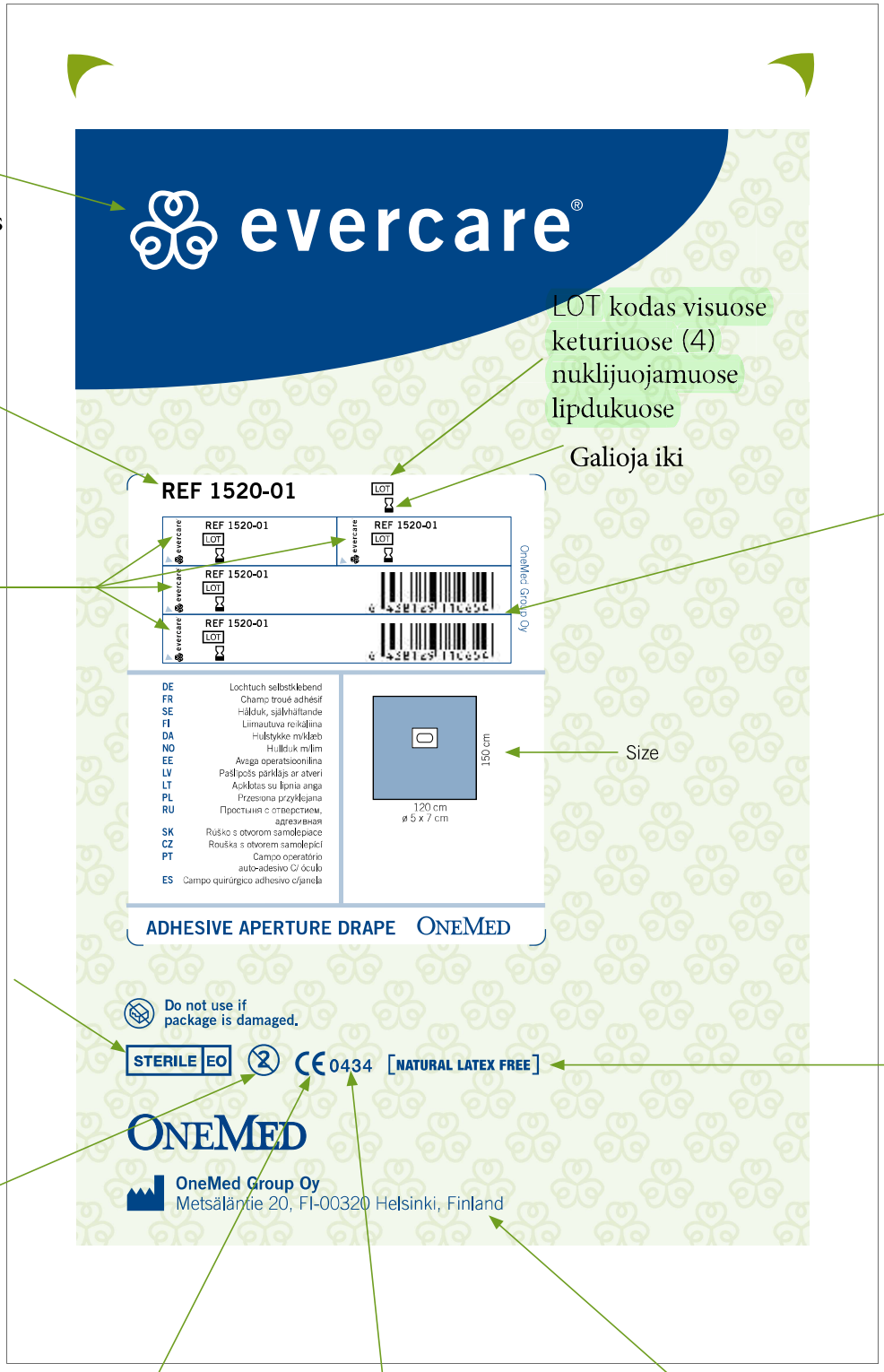
Material Chart



Complies to EN 13795.

- Absorbent and impermeable multilayer material
- Absorbent and impermeable 2-layer material
- Absorbent and impermeable reinforcement material (absorbent patch)
- Polyethylene film
- Elastic material
- Adhesive edge

INFORMACIJA ETIKETEJE
EN ISO 15223-1 ir EN 1041



Evercare® registruotas OneMed Group Oy prekinis ženklas

Ref. numeris

LOT kodas visuose keturiuose (4) nuklijuojamuose lipdukuose

Galioja iki

Visuose produktose yra keturi (4) nuklijuojami lipdukai atsekamumui

Brukšniniai kodai du lipdukai (2) nuklijuojami

Size

Sterilizacijos metodas: – eteleno oksidas EO

Sudėtyje nėra naturalios gumos latekso

Vienkartinio naudojimo

CE ženklinimas etiketėje: patvirtina kad, produktas atitinka Europos teisinius reikalavimus skirtus medicinos priemonėms

Identifikacinis sertifikavimo įstaigos numeris

Gamintojo kontaktinė informacija

210x120 mm

Antrinės pakuotės (dėžutės) lipdukas

evercare

DE	Sectio-Set
FR	Trousse de Césarienne
SE	Kejsarsnittset
FI	Sektiopakkaus
DA	Sectiosæt
NO	Keisersnittsett
EE	Keisrilõikekomplekt
LV	Ķeizargrieziena komplekts
LT	Cezario pjūvio rinkinys
PL	Zestaw do cięcia cesarskiego
RU	Комплект для кесарева сечения
SK	Set na cisársky rez
CZ	Set pro císařský řez
PT	Set cesariana
ES	Kit cesária

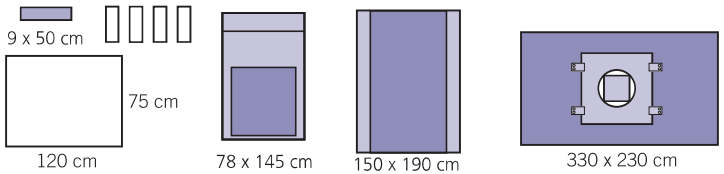
C-SECTION SET

REF 1261-02

evercare

REF 1261-02 LOT

PCS 5



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C-SECTION SET

2 CE 0434 STERILE EO

[NATURAL LATEX FREE]

ONEMED

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

6 438129 316841

The three-layer principle for packaging sterile products

The three-layer principle for packaging sterile products involves three layers: product packaging, departmental packaging, and transport packaging.

1) Product packaging:

- Clearly marked with type and size.
- Includes expiration date, batch number, and barcode with article number.
- Marking should indicate how to open the package.

2) Departmental packaging:

- Typically a carton showing expiration date, batch number, number of products, and article number.
- Designed to protect products and maintain sterility until use.

3) Transport packaging:

- Sturdy and fully covering carton.
- Marked with supplier's article number, contents, and quantity.
- Sterility marking visible after pallet loading.
- Should be openable without damaging departmental packaging.

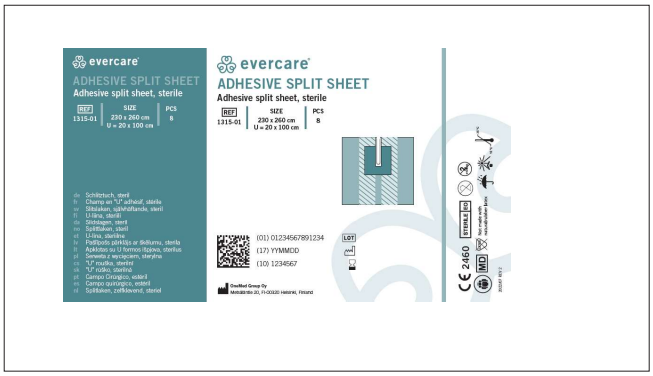
Product packaging | Departmental packaging | Transport packaging

Better view on label details on next page

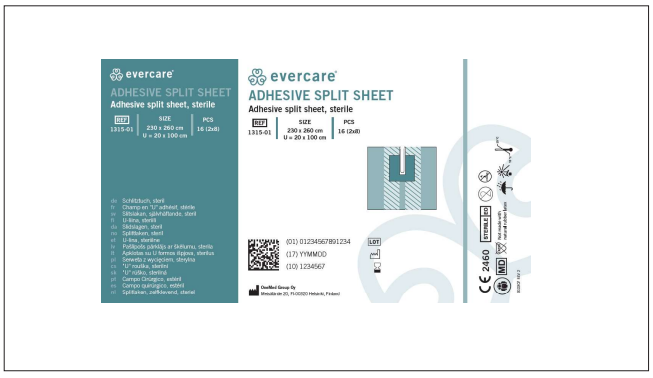
The three-layer principle for packaging sterile products

Product packaging

Departmental packaging



Transport packaging



REFs 1453-01, 1512-01, 1410-01, 1415-01, 1455-01, 1515-01, 1520-01, 1555-01, 1505-01, 1320-01, 1741-01, 1460-02, 1465-02, 1470-02, 1272-01, 1452-01, 1461-01, 1451-01, 1463-02, 1408, 1463-50, 1511, 1324-02, 1325-01, 1328, 1330-02, 1332-02, 1356-01, 1365-01, 1366-01, 1454-01, 1466, 1510-01, 1513-01, 1525-01, 1530-01, 1535-02, 1537-01, 1538-01, 1539-01, 1565-01, 1375-01, 1340-01, 1232-50, 1517, 1461-01

EU Quality Management System Certificate

Certificate no.:
10000510540-PA-NoMA-DNK

Initial certification date:
18 May 2022

Valid Until:
18 May 2027

This is to certify that the quality system of

ONEMED GROUP OY

Metsäläntie 20
00320 HELSINKI
Finland

For design, production and final product inspection/testing of:

Sterile Fixation bandages, Sterile support bandages, sterile gauze swabs and sponges, sterile nonwoven swabs and sponges, sterile absorbent dressings, sterile applicators, sterile surgical gowns.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 15 July 2022

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Alessandra Rhinna
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2623081, 2623077, 2623082	18 May 2022
1.0	Add devices marked in bold	2745294	15 July 2022

Products covered by this Certificate:

Product Description	Product Name	Class*
Sterile single use medical devices	Applicators, sterile Absorbent dressings, sterile Fixation bandages, sterile Support bandages, sterile Swabs and Sponges, gauze, sterile Swabs and Sponges, nonwoven, sterile Surgical Gowns, sterile **Instrument and Equipment drapes, sterile** **Surgical drapes, sterile** **Tube holders, sterile**	Class Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
OneMed Group Oy	Metsäläntie 20, 00320 Helsinki, Finland
OneMed Products AB	Tagenevägen 29, Box 50, SE-401 20 Göteborg, Sweden

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.