Product Data Sheet

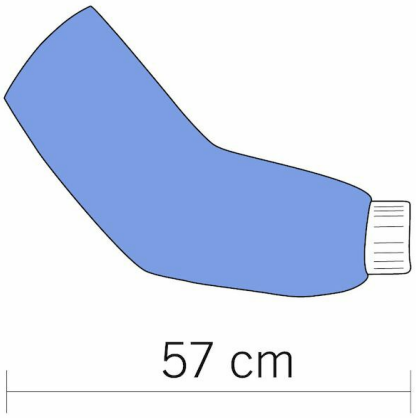
evercare® Arm cover

REF: 1398-01

evercare® Arm cover, sterile is a disposable arm cover with high quality cuff.

Key Features

- High quality cuff
- Complies to EN 13795-1 High performance critical product area requirements

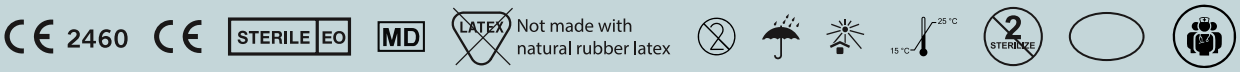


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1398-01	Arm cover, sterile, Blue	Length 57 cm	30 / 120

Sales Unit: Transport Carton

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
Cuff	Rib knitted, 100% PES, white
Elastic band at upper arm	Synthetic, natural latex free

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
1398-01	06438129110548	06438129310542	06438129510546

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.

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

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, sterile drapes, sterile tube holders.

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, 17 October 2022

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

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

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
2.0	Admin change	2720384	12 October 2022
3.0	Admin change	Not applicable	17 October 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
Evercare Medical 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.