EAN 8721008158013
Bloedarmoede, Vitaminen & Diabetes test

Product foto

CE gecertificeerde onderdelen

CE

greiner BIO-ONE

EU Declaration of Conformity

to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: N/A
Production Location:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	
Product / Product Group:	MiniCollect® CAT Serum (Sep) TUBE (for details please refer to page 2)	
BASIC-UDI-DI (GMN):	MiniCollect® CAT Serum Sep TUBE: 912001757G00000469X MiniCollect® CAT Serum TUBE: 912001757G00000459V	
Classification:	Class A according to Regulation (EU) 2017/746 of the european parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices, Annex VIII Classification Rules - Rule 5	
GMDN Code(s):	MiniCollect® CAT Serum Sep TUBE: 58138 MiniCollect® CAT Serum TUBE: 58140	

We herewith declare under our sole responsibility that the products specified above meet the provisions of the above-mentioned Regulation. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex IVof the Regulation (EU) 2017/746.

Standards / common specifications:
Refer to the list of applicable (harmonized) standards and common specifications in the Technical Documentation.

Kremsmünster, 20.05.2022

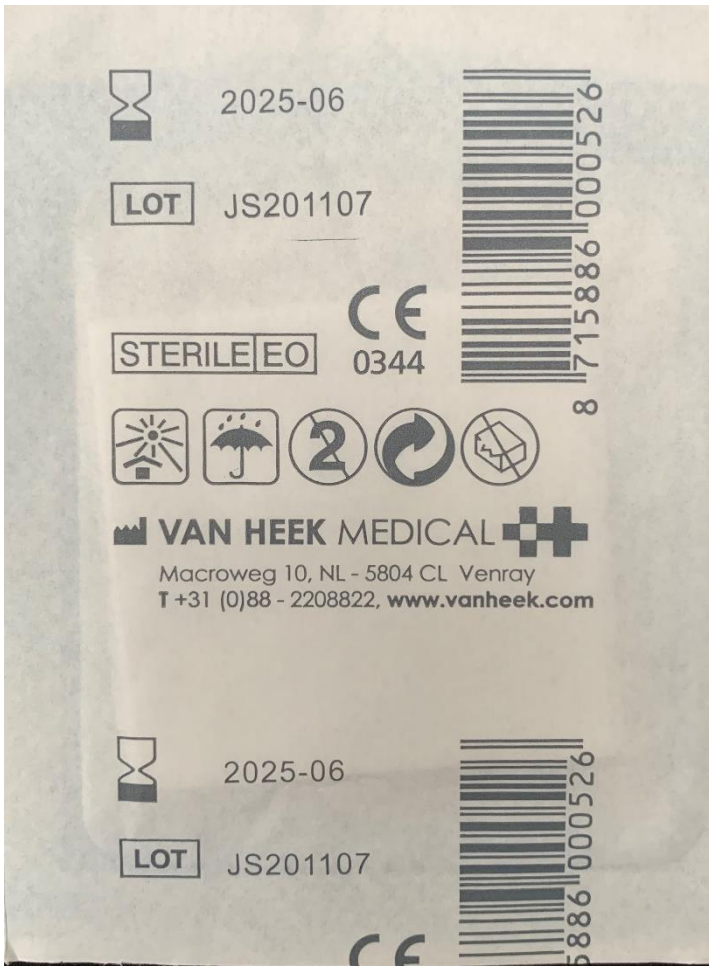
greiner QM bio-one

Georg Sambs
Quality Manager
Greiner Bio-One Austria

CE

greiner

PRODUCT GROUP	Product name - detailed product description	Item numbers
MiniCollect® CAT Serum Sep TUBE	MiniCollect® TUBE 0.5/0.8 ml CAT Serum Sep Clot Activator gold cap	450533
MiniCollect® CAT Serum TUBE	MiniCollect® TUBE 0.5 / 1 ml CAT Serum Clot Activator red cap	450534
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, pre-assembled with Carrier Tube 13x75	450548
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, pre-assembled with Carrier Tube 13x75	450549
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, paper label, pre-assembled with Carrier Tube 13x75	450568
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, paper label, pre-assembled with Carrier Tube 13x75	450569
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, ISLAB barcode label, pre-assembled with Carrier Tube 13x75	480148
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480548
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480568


2025-06
LOT JS201107
STERILE EO
CE 0344
8 715886 000526
VAN HEEK MEDICAL
Macroweg 10, NL - 5804 CL Venray
T +31 (0)88 - 2208822, www.vanheek.com
2025-06
LOT JS201107
CE
5886 000526

EC CERTIFICATE

Number: 2018306CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:
Allion B.V.
Macroweg 10
5804 CL Venray
The Netherlands

For the product category(ies)

Sterile wound dressings

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2018306CN, initially dated 1 June 2002
Addendum, initially dated 12 December 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 11 March 2023
Issued for the first time: 1 June 2002
Revised: 21 December 2018
Reissued: 28 September 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2018306CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile wound dressings

Issued to:

Allion B.V.
Macroweg 10
5804 CL Venray
The Netherlands

This certificate covers the following product(s):

- Absorbing dressings (Hekasorb / Hekapad AB02) (Class I sterile)
- Gauze Swabs (Hekapres Ko01) (Class I sterile)
- Non woven compresses (Hekasoft, NW01) (Class I sterile)
- First Aid dressing (VA09) (Class I sterile)
- EYE PAD (Class I sterile)

NOTE Allion B.V. uses Van Heek Medical as trade name for the above mentioned products

Initial date: 12 December 2002
Revision date: 28 September 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396


LOT 2101851
2024 08 10
HeltiQ
Plaster 19 x 72 mm
Importer: Koninklijke Utermöhlen NV, De Overweg 1, 8471 ZA Wolvega, The Netherlands, www.heltiq.com
Changzhou Hualian Health Dressing Co., Ltd. No. 55 Yuejin Road, Zoucu Town, 213144 Changzhou, Jiangsu, China
Shanghai International Holding Corp. GmbH (Europe) Effestraße 80, 20537 Hamburg, Germany

EC DECLARATION OF CONFORMITY

Manufacturer:
Name: Changzhou Hualian Health Dressing Co., Ltd.
Add: No.55 Yuejin Road, Zouqu Town, Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Non-sterile Bandage
Model: A-Elastic fabric, B-PE, C-PU
Size: 30mm×30mm, 30mm×40mm, 32mm×22mm, 38mm×16mm, 38mm×19mm, 38mm×38mm, 40mm×10mm, 45mm×10mm, 45mm×51mm, 55mm×19mm, 56mm×29mm, 57mm×15mm, 57mm×21mm, 60mm×18mm, 60mm×19mm, 62mm×36mm, 62mm×50mm, 63mm×25mm, 65mm×19mm, 65mm×40mm, 70mm×12mm, 70mm×18mm, 70mm×25mm, 70mm×70mm, 72mm×19mm, 72mm×25mm, 72mm×30mm, 72mm×38mm, 72mm×45mm, 76mm×19mm, 76mm×25mm, 76mm×38mm, 76mm×45mm, 76mm×50mm, 76mm×76mm, 80mm×58mm, 82mm×25mm, 83mm×57mm, 88mm×38mm, 95mm×50mm, 95mm×65mm, 100mm×30mm, 100mm×60mm, 101mm×44mm, 101mm×50mm, 101mm×76mm, 400mmx1000mm, 600mmx1000mm, 800mmx1000mm, 400mmx5000mm, 600mmx5000mm, 800mmx5000mm, Φ22mm, Φ25mm

Intended use:
Non-sterile bandage is mainly used for small wound and cortical trauma care.

Product Picture:



A- Elastic fabric B-PE C-PU

Risk Class of the Device: The medical device has been assigned to class Ⅰ, Rule 4 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745.
UMDNS code: 10276
Basic UDI-DI: 69417626009VD
Standard: /
Conformity Assessment Route: Self-declaration of Conformity

We herewith declare that the above-mentioned products meet the provisions of the following Medical Device REGULATION (EU) 2017/745. All technical documentations are retained under the promises of the manufacturer.
Changzhou Hualian Health Dressing Co., Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:
Medical Device REGULATION (EU) 2017/745

Notified Body: /

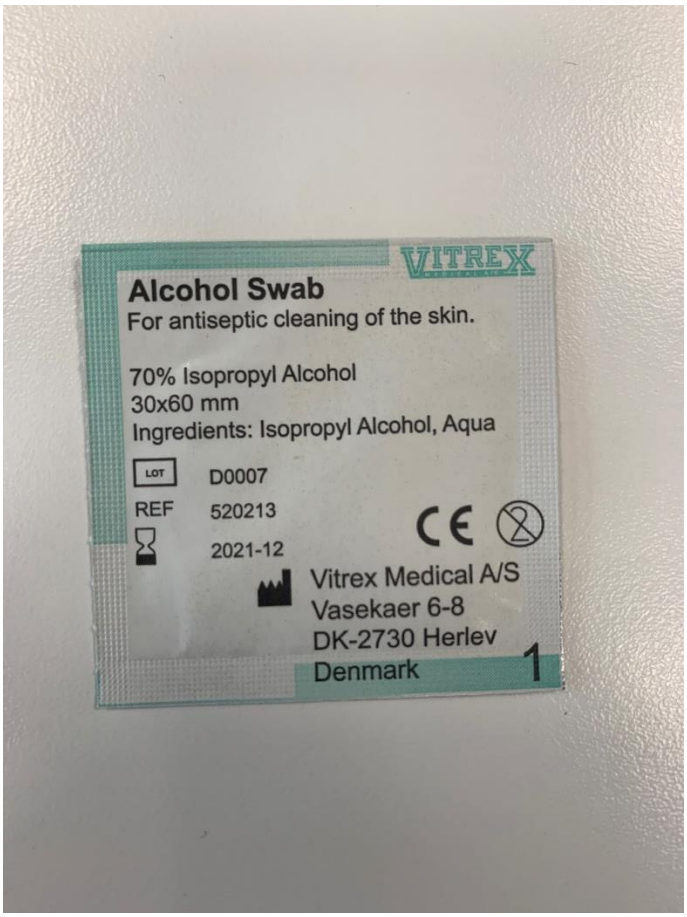
Identification Number：/

CE Certificate No.： Not yet
Date CE mark was affixed：/

Valid until：/

Position：Manager Representative
Date： 2021-01-20

Name: Huang Liqing
Place：Changzhou City, Jiangsu Province


VITREX
Alcohol Swab
For antiseptic cleaning of the skin.
70% Isopropyl Alcohol
30x60 mm
Ingredients: Isopropyl Alcohol, Aqua
LOT D0007
REF 520213
2021-12
Vitrex Medical A/S
Vasekaer 6-8
DK-2730 Herlev
Denmark
1

VITREX

EC Declaration of Conformity

Manufacturer: Vitrex Medical A/S
Vasekaer 6-8
2730 Herlev
Denmark

SRN (Single Registration Number): N/A

Product REF	Product Name	Basic UDI-DI
520213	Vitrex® Alcohol Swabs, 70% Isopropyl Alcohol	15706860202135
521213	Vitrex® Alcohol Swabs, 82% Ethanol	15706860212134
522213	Vitrex® Alcohol Swabs, 82% Ethanol with 0.5% Chlorhexidine	15706860222133

Classification: Class I, according to annex VIII (EU) MDR 2017, rule 1

Conformity assessment route: EC conformity declaration according to annex II and III of the Regulation (EU) MDR on medical devices.

We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) 2017/745 on medical devices.

This EU declaration of conformity is issued under the sole responsibility of Vitrex Medical A/S.

Signature:

VITREX MEDICAL A/S
Vasekær 6-8
DK-2730 Herlev
TEL: +45 4494 7011
FAX: +45 4453 1711
E-MAIL: VITREX@VITREX.DK

Peter Jørgensen
Quality and System Manager

Place and date of Issue

Herlev, January 13, 2022

CTI group

Vitrex Medical a/s
Vasekær 6-8 · DK 2730 Herlev · Denmark
Phone +45 4494 7011 Fax +45 4453 1711
vitrex@vitrex.dk · www.vitrexmedical.com
CVR No: 14728732 · VAT no. DK 15341939


BD Microtainer®
Contact-Activated Lancet
For Capillary Blood Collection • За вземане на капилярна кръв • Pro odběr kapilární krve • Til kapillær blodprøvetagning • Zur kapillären Blutentnahme • Για συλλογή τριχοειδικού αίματος • Para la extracción de sangre capilar • Kapillaarvere kogumiseks • Kapillaariverinäytteitä varten • Pour prélèvement de sang capillaire • Za vađenje krvi iz kapilare • Kapilláris vér vételéhez • Fyrir blóðtöku úr æð • Per il prelievo di sangue capillare • Қылтамырдан қан алу үшін • 모세혈 채집용 • Skirta kapiliariniam kraujui imti • Asiņu savākšanai no kapilāriem • Voor capillaire bloedafname • Voor capillaire bloedafname • Do pobierania krwi kapilarnej • Para Colheita de Sangue Capilar • Pentru recoltarea sângelui capilar • Для взятия капиллярной крови • Na odber kapilárnej krvi • Za odvzem kapilarne krvi • För kapillär provtagning • Kilcal Kan Toplanmasi için • Для взяття капілярної крові • 用于采集毛细血管血液
1
2
3
4
5
UNIVERSAL PRECAUTIONS: Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) in accordance with the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (e.g. through a puncture injury) since samples may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector if the blood collection device provides one. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
0050
STERILE R
Rx Only (USA)
Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland
Technical Questions? www.bd.com/vacutainer or email vacutainer_techservices@bd.com
Call Toll-Free 1.800.631.0174 (USA Only)
U.S. Patents Nos. D532,517, D538,934, Patent Pending
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Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

The National Standards Authority of Ireland as a duly designated Notified Body, (identification number 0050), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)

APPROVES THE QUALITY SYSTEM APPLIED BY

Becton, Dickinson and Company Limited

Pottery Road
Dun Laoghaire
Co Dublin
Ireland

to the Product Family

Manual blood lancet, single-use (BD Microtainer® Contact-Activated Lancets)

GMDN Code: 61578

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V. The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of Conformance for this product family is hereby authorized.

Registration Number:	**252.910**
Original Approval:	**18 April 2013**
Last Amended on:	**8 January 2019**
Remains valid until:	**17 April 2023**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner .
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.