

8721008158136
SOA test Syphilis/Leus

Product foto



CE gecertificeerde onderdelen





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 SRN: N/A
Bad Haller Straße 32
4550 Kremsmünster
Austria

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 IV of 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




Georg Sams
Quality Manager
Greiner Bio-One Austria



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



VAN HEEK MEDICAL 

Macroweg 10, NL - 5804 CL Venray
T +31 (0)88 - 2208822, www.vanheek.com



2025-06

LOT

JS201107



CE



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

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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

1/1

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, NWD1) (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.

A handwritten signature in blue ink, appearing to read "B.T.M. Holtus".

B.T.M. Holtus
Managing Director

A handwritten signature in blue ink, appearing to read "J.A. van Vugt".

J.A. van Vugt
Certification Manager

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396







Plaster 19 x 72 mm

Importer: Kordhisa Liermthuis NV, De Chering 1, 8471 ZA Vlodrop, The Netherlands, www.heltiq.com
 Changzhou Huilian Health Dressing Co., Ltd. No. 25 Yuejin Road, Zuyao Town, 213144 Changzhou, Jiangsu, China
 Shanghai International Holding Corp. GmbH (Europä. Effizienz AG), 20037 Hamburg, Germany







Plaster 19 x 72 mm

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 Shanghai International Holding Corp. GmbH (Europä. Effizienz AG), 20037 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, 400mm×1000mm, 600mm×1000mm, 800mm×1000mm, 400mm×5000mm, 600mm×5000mm, 800mm×5000mm, 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

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

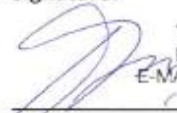
Classification: Class I, according to annex VIII (EU) MDR 2017, rule 1

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.

VITREX MEDICAL A/S
Signature: Vasekaer 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

 **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 vadenje 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 odzmem
kapilárne krvi • För kapillär provtagning • Kılcal Kan Toplanması için • Для взятия
капиллярной крови • 用于采集毛细血管血液



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.

     **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
BD, BD Logo and all other trademarks are property of Becton, Dickinson and Company. ©2012 BD Made in Poland



NSAI

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.