

Vitrex® Steel General Purpose Capillary Blood Lancet

Technical Data Sheet

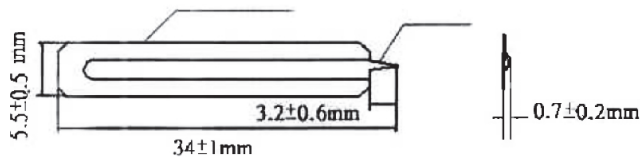
PRODUCT:

Vitrex steel general purpose capillary blood lancets are used to carry out skin punctures, in order to collect micro-samples of capillary blood.

- Sterile and disposable
- Made of stainless steel
- Gamma irradiation by cobalt
- Shelf life 5 years

The dimensions:

- Length: 34.0 ±1.0 mm
- Width: 5.5 ±0.5 mm



TECHNICAL SPECIFICATIONS:

Product	Description	Article No.
Vitrex Steel - standard	Flat blade sterile lancet	350213
Vitrex Steel - allergy	Flat blade sterile lancet	365213

MATERIAL:

The materials used to manufacture our Vitrex safety lancets are Medical grade:

Component	Material
Needle	Stainless Steel Grade X 5 Cr18Ni9 to DIN 17440

PRINT:

The terminology, graphic symbols and information applied to this medical equipment comply with EN ISO 15223-1:2016.

PACKAGING:

The inner box is made of white cardboard and the outer carton is made of corrugated cardboard. Each box contains batch number, expiration date and sterilization information.

- An inner box contains 100 individual Vitrex safety lancet units.
- One outer carton contains 10 inner boxes.



Inner Box

Length	Width	Height	Quantity
11 cm	6 cm	3 cm	200 pcs.

Packaging:

Primary packaging:	200 pcs.
Secondary packaging:	10,000 pcs.
Transit packaging:	40,000 pcs.
Pallet:	720,000 pcs.

LANGUAGES:

The labels contain 13 languages and comply accordingly to the European directive and may be sold in countries where one of these languages are accepted by national law.:

- Danish
- Spanish
- Italian
- Arabic
- Greek
- Swedish
- German
- Portuguese
- Finnish
- English
- French
- Russian
- Dutch

QUALITY:

- Manufactured in accordance with ISO 9001:2015 and ISO 13485:2016.
- Complies with Annex II, (Excluding Section 4) of the Directive 93/42 EEC.
- Sterilization by gamma radiation.

CHARACTERISTICS:

- Shelf life-time: 5 years
- Disposable



Vitrex Medical a/s

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Phone +45 4494 7011

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www.vitrexmedical.com





Vitrex Steel

General Purpose Capillary Blood Lancet

Vitrex Steel lancets are traditional handheld, flat and stainless steel blood lancets for general purpose use. The steel lancets are available in standard and in allergy version.

LOW COST

Simple, flat, steel lancet.

SAMPLE VOLUME

Excellent blood flow.

HIGH QUALITY

Hardened surgical steel.

MINIMUM DISCOMFORT

Modern assymetric design.

STERILE

Sterilised by gamma radiation to EN 556 and EN ISO 11137.

Technical Specifications

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Shelf life 5 years



Transit packaging

Pallet

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 Transit packaging: 40,000 pcs.
 Pallet: 720,000 pcs.



BUREAU
VERITAS

Bureau Veritas Certification

Vitrex Medical A/S

Vasekær 6-8, 2730 Herlev, Denmark

This is a multi-site certificate, additional site(s) are listed on the next page(s)

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

ISO 9001:2015

Scope of certification

Development, manufacture and sales of single use glass and plastic capillary tubes and accessories for diagnostic use. Marketing and sales of blood lancets and accessories for blood sampling and diagnostic. Marketing and sales of sutures, Hypodermic Syringes, Hypodermic needles, Cannulas, Needles, Diabetic in-vitro medical devices and diagnostic kits.

Original Cycle Start Date:	14-06-2000
Expiry date of previous cycle:	NA
Certification/Recertification Audit date:	NA
Certification/Recertification cycle start date:	18-06-2021
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	17-06-2024

Certificate No.:	DK014690	Version:	2	Issue Date:	18-03-2022
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Philip Absalonsen



DANAK

SYSTEM Reg.nr. 5005

Certification Office: Bureau Veritas Certification Denmark A/S
Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call: (+45) 77 311 000.





BUREAU
VERITAS

Bureau Veritas Certification

Vitrex Medical A/S

Standard

ISO 9001:2015

Scope of certification

Site Name/location	Site Address	Site Scope
Vitrex Medical A/S (Head Office)	Vasekær 6-8, 2730 Herlev, Denmark	Development, manufacture and sales of single use glass and plastic capillary tubes and accessories for diagnostic use. Marketing and sales of blood lancets and accessories for blood sampling and diagnostic. Marketing and sales of sutures, Hypodermic Syringes, Hypodermic needles, Cannulas, Needles, Diabetic in-vitro medical devices and diagnostic kits.
Vitrex Medical A/S, Smedeholmen	Smedeholmen 15-17, 2730 Herlev, Denmark	

Certificate No.: **DK014690**

Version: **2**

Issue Date: **18-03-2022**

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Original Cycle Start Date:	14-06-2000
Expiry date of previous cycle:	NA
Certification/Recertification Audit date:	NA
Certification/Recertification cycle start date:	15-06-2021
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	14-06-2024

Certificate No.:	DK014689	Version:	2	Issue Date:	18-03-2022
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Bureau Veritas Certification

Vitrex Medical A/S

Standard

ISO 13485:2016

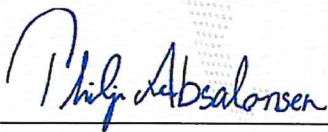
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