

PRODUCT INFORMATION

VACUETTE® QUICKSHIELD Complete PLUS

SPECIFICATION

INTENDED USE

The **VACUETTE®** QUICKSHIELD Complete PLUS is intended to be used only with **VACUETTE®** Blood Collection Tubes as a system in routine venipuncture procedures. They are for single-use only and should only be used by properly trained healthcare professionals only in accordance with the currently valid instructions for use (please refer to www.gbo.com).

PRODUCT DESCRIPTION

The sterile **VACUETTE®** QUICKSHIELD Complete PLUS is a single packed QUICKSHIELD Safety Tube Holder with pre-threaded **VACUETTE®** VISIO PLUS Blood Collection Needle in a blister pack. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognise successful vein penetration. The **VACUETTE®** QUICKSHIELD Complete PLUS is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. It does not contain any component made of natural rubber latex.

CLASSIFICATION OF DEVICE

EU classification: medical device (acc. to MDD 93/42/EEC)
MDD Class IIa

CE-MARK / APPLIED STANDARDS / PRODUCT CERTIFICATIONS

All standards required for CE certification are fulfilled.
Notified Body: TÜV Süd, Germany
CE-Mark, US FDA, all others individual per country

FIELD OF APPLICATION

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MATERIALS

Product Part	Material (basic description)
Holder	Polypropylene
Quickshield	Polypropylene and green colour pigment
Needle hub, container, cap	Polypropylene
Siliconisation of needle	Silicone oil
Glue / adhesive	Epoxy (resin)
Rubber sleeve	Synthetic rubber compound
Needle (cannula)	Stainless steel SUS-304
Filter	Polyethylene ultra-high molecular weight (PE-UHMW) Acrylic acid / superabsorbent polymers

LEGAL MANUFACTURER

Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

PRODUCER (PHYSICAL MANUFACTURER)

Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
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STERILITY

Sterility Level: Sterile (SAL 10⁻⁶)
Method: Irradiation (E-Beam)

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PACKAGING

- Graphical symbols used: according to EN ISO 15223-1, for use in the labelling of medical devices.
- Package: Blister: plastic material, paper top.
- Shipping carton: cardboard.

	Single package	Shelf box	Shipping carton
VACUETTE® QUICKSHIELD Complete	1 pc.	30 pcs	300 pcs

LABELLING

- Graphical symbols used: according to EN ISO 15223-1, for use in the labelling of medical devices.
- Labelling information: according to the requirements of the relevant EU and FDA guidelines.

Lot numbers

For example "G170237W". Meaning of digits:

Digits 1 (Letter)	Digit 2-3	Digits 4-5	Digits 6-8
G	17	02	37W
Represents actual manufacturing location. G = Greiner plant at Rainbach (Austria)	Represents year of manufacturing. 17 = 2017	Represents manufacturing month. 02 = February	Chronological numbering / lettering; no specific meaning

IFU as part of labelling

	Available (Yes / No)	Enclosed with product (Yes / No)	Available via Website (Yes / No)
Graphic IFU	Yes (printed on packaging)	Yes (printed on packaging)	No
Full (verbal) IFU	Yes	No	Yes

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Complete PLUS

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SHELF LIFE

3 years from date of manufacturing. Expiry date is 3 years minus one day from the manufacturing date.

RECOMMENDED STORAGE CONDITIONS

4°-36°C / 40°-97°F.

ADDITIONAL PRODUCT INFORMATION

Additional information concerning materials

- ☞ Product is not made with DEHP
- ☞ Product is not made with natural rubber latex

Additional information for use of the device

The safety shield is rotational and allows the preferred positioning.

NEEDLE INFORMATION

Gauge Type of needle	wall
21G	Thin wall
22G	Thin wall

RECOMMENDED COMPONENTS FOR USE WITH THE DEVICE

- ☞ **VACUETTE®** Blood Collection Tubes