VPA Prüf- und Zertifizierungs GmbH
Papenberger Straße 49 | D-42859 Remscheid

Greiner Bio One GmbH

Bad Haller Str. 32
A-4550 Kremsmünster

Austria

- Produktprüfung
- Produktzertifizierung
- Werkstofflabor
- Fachgutachten
- Schadensanalysen

Expert Opinion

20.06.2017

on the suitability of the products

- **VACUETTE® QUICKSHIELD Complete PLUS**
- **VACUETTE® QUICKSHIELD Safety Tube Holder**
- **VACUETTE® VISIO PLUS Needle**

by

Greiner Bio-One GmbH
Bad Haller Str. 32, A-4550 Kremsmünster

for the prevention of needlestick injuries (NSI) during blood collection, as well as the compliance of the product with the safety requirements of the *Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU* and the *Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation by the European Biosafety Network.*

Commissioned Body

VPA Prüf- und Zertifierungs GmbH

Dipl.-Chem. Thomas Schochow

Papenberger Str. 49
42859 Remscheid

1 Scope of the expert opinion

Needle-stick injuries expose the affected person to risks of infection due to transfer of pathogens in contaminated blood. The prevention of needle-stick injuries therefore has high priorities for safe working conditions.

The purpose of this expertise is the examination of the presented products **VACUETTE® QUICKSHIELD Complete PLUS** as well as its components **VACUETTE® QUICKSHIELD Safety Tube Holder** and **VACUETTE® QUICKSHIELD VISIO PLUS Needle** in combination with the separate in regard of their capability to prevent accidental needle-stick injuries for healthcare workers during blood collection. It also has to be established whether the combined products meet the requirements of the

- *Framework agreement on prevention from sharp injuries in the hospital and healthcare sector*
- *European Council Directive 2010/32/EU* (adaptation of aforementioned framework agreement)
- *European Biosafety Network Implementation Guidance*
- *German Technical Rule for Biological Agents TRBA 250* section 4.2.5. (4) 4

For this purpose, the device will be used and reviewed as per the manufacturer's instructions for use (Intended Use).

In addition, the safety of the product regarding "foreseeable misuse" is also assessed within reasonable terms, by examining the devices during intuitive usage or intentional manual deactivation of safety mechanisms, i.e. use of the product in a manner not intended by the manufacturer or seller of the product.

2 Regulations

2.1 Framework Agreement on prevention from sharp injuries[1]

In 2009 the framework agreement was signed by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Public Services Union (EPSU) to prevent sharp injuries in the hospital and healthcare sector. These organizations are the recognized European Social Partners in the hospital and healthcare sector, and therefore the agreement aims to reduce all risks to healthcare workers caused by injuries from any sharps.

> *The purpose of this agreement is*
>
> - *to achieve the safest possible working environment for employees in the hospital and healthcare sector;*
> - ***to prevent injuries to workers caused by all types of sharp medical objects and instruments which are able to cut and/or prick;***
> - *to protect workers at risk;*
> - *to set up an integrated approach to assessing and preventing risks as well as to training and informing workers;*
> - *to put in place response and follow-up procedures.*

[1] HOSPEEM & ESPU, Framework agreement on prevention from sharp injuries in the hospital and healthcare sector, 2009

The agreement defines principles to reduce the risk of sharps injuries, ranging from education and training of healthcare workers to the provision of helpful mind sets and working environments.
Several topics are covered in-depth, providing strategies to improve all processes regarding possible risks of sharps injuries:

- *Risk assessment*
- *Elimination, prevention and protection*
- *Information and awareness-raising*
- *Training*
- *Reporting*
- *Response and follow-up*

This framework agreement mentions safety devices in clause 6, and therefore is relevant for the assessment of said devices:

> *Where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection, workers´ exposure must be eliminated by taking the following measures, without prejudice to their order:*
>
> - *Specifying and implementing **safe procedures for using and disposing of sharp medical instruments** and contaminated waste. These procedures shall be regularly reassessed and shall form an integral part of the measures for the information and training of workers referred in clause 8;*
> - *Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, **providing medical devices incorporating safety-engineered protection mechanisms**; [...]*

2.2 European Council Directive 2010/32/EU[2]

Directive 2010/32/EU adapts the *framework agreement* (2.1) and annexed the whole agreement. Thus, the intentions of the agreement are implemented on EU level.

However, the goals of the Directive itself have to be implemented in each EU country individually in their own laws.

[2] Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU

2.3 European Biosafety Network Implementation Guidance[3]

The European Biosafety Network was established after the final adoption of the *Council Directive 2010/32/EU*. Its principal objective is the improvement of the safety of patients and healthcare workers by elimination of sharps injuries. This open network promotes of best practices when using sharps and provides guidance reducing sharps injuries at EU level based on the Council Directive on sharps injuries. Other measures include the training and education od healthcare workers as well as the providing safety engineering technologies.

The document *Prevention of Sharps Injuries in the Hospital and Healthcare Sector - Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation* provides guidance on the practical implementation of the Directive 2010/32/EU. The principles described in 2.1 are therefore relevant in this document as well.

One of the principles explicitly mentioned in the Guidance document involves the hierarchy of measures concerning the protection of healthcare workers as referenced in the Directive itself. For example, the use of safety-engineered protection mechanisms has higher priority over the use of personal protective equipment.

According to the Guidance document, the function of the safety mechanism should be evaluated under the following criteria:

- *The device must not compromise patient care;*
- *The device must perform reliably;*
- *The safety mechanism must be an integral part of the safety device, not a separate accessory;*
- *The device must be easy to use and require little change of technique on the part of the health professional;*
- *The activation of the safety mechanism must be convenient and allow the care-giver to maintain appropriate control over the procedure;*
- *The device must not create other safety hazards or sources of blood exposure;*
- *A single-handed or automatic activation is preferable;*
- *The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual sign to the health professional;*
- *The safety mechanisms should not be easily reversible once activated.*

The provided products are therefore tested against these criteria to determine whether the product and its safety mechanism comply with the requirements set by the Guidance document of the European Biosafety Network.
Products meeting these criteria are considered to be safety-engineered medical devices.

[3] European Biosafety Network, Prevention of Sharps Injuries in the Hospital and Healthcare Sector - Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation, 2010

2.4 TRBA 250 - Biological agents in health care and welfare facilities

German *Technical Rule for Biological Agents (TRBA) 250*[4] is a compilation of rules, which reflects the state of the art, the state of occupational health and occupational hygiene as well as other scientific knowledge regarding the involvement of biological agents. This document lists concrete terms how to fulfil the requirements set by the *Biological Agents Ordinance*[5], which applies to all activities involving biological agents, is in itself the national implementation of the *Council Directive 2010/32/EU* and is part of the *Safety and Health at Work Act (Arbeitsschutzgesetz)*[6].
In this context, the safe blood collection is covered by the *TRBA 250* as a non-targeted activity with regular contact with body fluids, resulting in the assigned "Protection level 2". Therefore, several requirements for safe use of medical devices are listed.

Consistent with the risk assessment and hierarchy of protective measures of either *Council Directive 2010/32/EU* as well as the *German Safety and Health at Work Act*, healthcare workers are to be protected, first and foremost, by using the best available technology (e.g. safety engineered devices) before education/training of staff or personal protective equipment.

TRBA 250, as mentioned before, contains state of the art knowledge regarding the handling of biological agents, and therefore also lists safety measures to prevent needle-stick injuries.

> *4.2.5 (3) Priority is to be given to selecting suitable and safe work processes and equipment that render the use of pointed and sharp medical instruments superfluous. [...]*
>
> *(4) Should it be necessary to use pointed and sharp medical instruments,* ***it is essential to use working equipment that has a safety mechanism*** *(hereinafter "safety equipment"), complies with numbers 1 to 7 below, and presents no or only a minor risk of punctures and cuts, provided this is technically possible and necessary for preventing a risk of infection.*
>
> 1. *[...]*
> 2. *[...]* ***safety equipment is to be used*** *for all activities where there is or can be assumed to be a risk of infection due to possible puncture injuries. In particular, these activities include:*
>   *– taking blood samples, [...]*
> 3. *For all other activities that do not fall under points 1 and 2, the employer must assess the risk of accident and infection in the risk assessment and take appropriate measures. If a risk of infection must be assumed and this cannot be minimized through organizational and*

---

[4] Technical Rule for Biological Agents 250, Biological agents in health care and welfare facilities (TRBA 250) (Edition: March 2014, GMB 2014, No. 10/11 of 27.03.2014, p. 206; Last amended: GMBl 2015 No. 29 of 21.07.2015, p. 577)

[5] Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (Biological Agents Ordinance - BioStoffV) of 15 July 2013 (Federal Law Gazette [BGBl.] Part I p. 2514)

[6] Safety and Health at Work Act of 7 August 1996 (Federal Law Gazette I p. 1246), as last amended by Article 8 of the Act of 19 October 2013 (Federal Law Gazette I p. 3836)

personal measures, ***priority is to be given to the use of safety equipment.***

4. ***Safety equipment for the prevention of punctures and cuts must have the following properties:***
   - *It must put neither patients nor workers at risk.*
   - *It must be easy to use and application-oriented.*
   - *The safety mechanism is an integral part of the system and is compatible with other accessories.*
   - *The activation of the safety mechanism must:*
     - *be self-triggering or allow single-handed operation;*
     - *be possible immediately after use;*
     - *rule out subsequent use;*
     - *be indicated by a clear signal (tactile, visible or audible).*

The provided products are therefore tested according to the requirements of *TRBA 250* 4.2.5 (4) 4. Devices meeting these criteria are considered to be state of the art safety equipment.

3 Facts and findings

The product **VACUETTE® QUICKSHIELD Complete PLUS** is a pre-assembled combination of **VACUETTE® QUICKSHIELD Safety Tube Holders** wand **VACUETTE® VISIO PLUS Needles.** It is used for blood collection and features a built-in safety mechanism which originates from the **VACUETTE® QUICKSHIELD Safety Tube Holder**.

After use, the attached shield is pushed over the contaminated needles until it locks onto the needle, therefore providing a safety mechanism to prevent further exposure of the contaminated needle and subsequent risk of needle-stick injury.

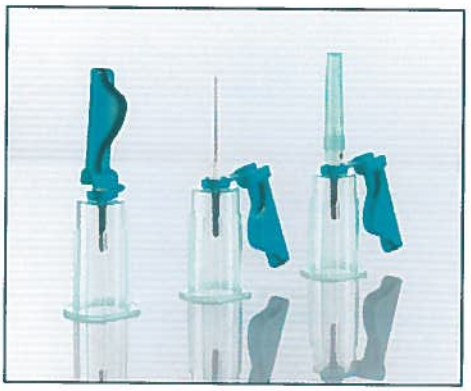


Figure 1: VACUETTE® QUICKSHIELD Complete PLUS

3.1 Range of assessed products

Art.-No.	Product
450226	**VACUETTE® QUICKSHIELD Complete PLUS 22Gx1" (LOT G1509374)**
450228	VACUETTE® QUICKSHIELD Complete PLUS 22Gx1½"
450235	VACUETTE® QUICKSHIELD Complete PLUS 21Gx1"
450239	VACUETTE® QUICKSHIELD Complete PLUS 21Gx1½"
450230	**VACUETTE® QUICKSHIELD Sicherheitsröhrchenhalter (LOT G1702356)**
450040	VACUETTE® VISIO PLUS Needle 21G x 1½"
450041	**VACUETTE® VISIO PLUS Needle 22G x 1½" (LOT 15K27B)**
450042	VACUETTE® VISIO PLUS Needle 21G x 1"
450043	VACUETTE® VISIO PLUS Needle 22G x 1"

Table 1: Products included in this expertise – VACUETTE® QUICKSHIELD Complete PLUS

Due to the combination of the same safety mechanism of the **VACUETTE® QUICKSHIELD Safety Tube Holder** (450230) and different **VACUETTE® VISIO PLUS Needles**, the presented pre-assembled product combination (Art.-No. 450230 & 450043) should have the same safety properties as every other needle variant. Therefore, the expertise for the entire product line is based on the examination of this article (450226), as well as supporting examinations of different needle variants (length, diameter) of other tests.

3.2 General findings

The product **VACUETTE® QUICKSHIELD Complete PLUS** is manufactured by:

Greiner Bio-One GmbH
Bad Haller Str. 32
A-4550 Kremsmünster

They display the CE marking (Notified Body 0123, TÜV SÜD Product Service GmbH Zertifizierstellen, Ridlerstraße 65, 80339 München). Although the product is a medical device under *European Council Directive 93/42/EEC* (Medical Devices Directive), the verification of compliance of **VACUETTE® QUICKSHIELD Complete PLUS** or **VACUETTE® VISIO PLUS Needles** is at no time part of this report.

3.3 Manufacturer's instructions for use

The manufacturer recommends the equipment to be used by a trained user as well as immediate disposal of contaminated, unsealed or deformed items.
The protective cap of the **VACUETTE® VISIO PLUS Needle** is pulled off. The safety shield of the holder can now be repositioned to the users liking, the black point marking the bevel of the needle tip.
After the removal of the last collection tube from the holder, the needle is retracted out of the veins of the patient. The safety mechanism is activated by pushing the shield of the holder over the needle – either with a finger of the hand holding the needle/holder combination or by pressing the shield on a firm surface. The safety mechanism should lock with an audible click, upon which the needle/holder combination is to be safely disposed.

3.4 User experiences

The repositionable shield makes it comfortable for venipuncture. The process of blood collection itself is not different from usual processes. If the instructions are followed and the activation of the safety mechanism takes place immediately after the completed blood collection, the procedure is safe and the risk of needle-stick injuries is reduced. The activation of the safety mechanism can be heard but the haptic feedback is weak.
After the activation of the shield, the needle is safely contained under the shield.

3.5 Deactivation of safety mechanisms

The safety mechanism of the **VACUETTE® QUICKSHIELD Safety Tube Holder** could not be opened again without using tools.
Upon opening the safety shield of a locked mechanism on a 1,5" needle, the needle is bent without

exposing the tip. If the safety shield is opened after securing a 1" needle, the needle is bent and only at the end of the 180° movement of the shield the bent needle slips out of the retaining flap, possibly exposing the tip for needle-stick injury.

4 Evaluation of facts and findings

4.1 General

During the process of blood collection – including the disposal – exists a risk of needle-stick injuries due to the use of sharp objects (needles). The prevention of NSI therefore reduces the risk of potentially serious infection of healthcare workers. The consequent use of safety-engineered devices - in combination with training, the ban of recapping, and safe disposal – has been shown to significantly lower the risk of needle-stick injuries. Legal acts and ordinances, both on EU as well as national level, give requirements and suggestions for safety devices.

Given the training of healthcare workers in safe usage and disposal as well as providing ways to safely dispose used devices, the use of the examined devices is assessed according to the aforementioned regulations.

4.2 Council directive 2010/32/EU & Framework agreement

Due to the annexed framework agreement within the Directive the requirements of both legal documents are evaluated at once.

The combination of **VACUETTE® QUICKSHIELD Safety Tube Holder & VACUETTE® VISIO PLUS Needles,** sold pre-assembled as **VACUETTE® QUICKSHIELD Complete PLUS,** does meet all requirements of aforementioned documents.

- ***[The purpose of this agreement is] to prevent injuries to workers caused by all types of sharp medical objects and instruments which are able to cut and/or prick;***
  Though no requirement of the framework agreement regarding the product itself, the intention of the framework agreement is met due to the encapsulation of the sharp tip of the needle. Thus, during the complete process of blood collection, the risk of needle-stick injuries is greatly reduced.
- ***[Clause 6] Specifying and implementing safe procedures for using and disposing of sharp medical instruments and contaminated waste***
  The procedure of blood collection itself is safe if handled according to the Instructions of Use, thus meeting the requirements of the framework agreement. Given the disposal into safe sharps containers, the process of disposal by the healthcare worker into the container is safe due to the complete encapsulation after activation of the safety mechanism.
- ***[Clause 6] Eliminating the unnecessary use of sharps by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms***
  Even if the venipuncture itself, as well as a short period in the retraction phase, exposes the needle for possible touch by the user, the user should have his hand located on safe locations on the holder/shield during handling, thus being able to push the shield over the needle immediately after use. If the mechanism is locked, the risk of needle-stick injuries is reduced by the safety-engineered protection mechanism.

A shorter needle (1" or less) could possibly be exposed again if the used equipment is not disposed immediately and if there is a force able to open the safety shield in a rotation manner for ca. 180°. The risk of both situations (longer time until disposal and intention to/possibility of completely open the safety shield) is minimized by the Instructions of Use by the manufacturer, which clearly states:

- *Recommended training of the user according to Instructions of Use*
- *Disposal as soon as possible after use*
- *Explicit restriction of forced release of the safety mechanism*
- *Restriction to bend needles or use bent needles*

Therefore, the expert deems the probability of misuse to be very low, if **VACUETTE® QUICKSHIELD Complete PLUS** equipment is used according to the Instructions of Use and is disposed immediately after use, lowering the risk of needle-stick injuries until disposal.

4.3 European Biosafety Network Implementation Guidance

The requirements of the Implementation Guidance provided by the European Safety Network are met.

- ***The device must not compromise patient care***
  The combined device can be used similar to normal needles, therefore being no threat to either patient or user.
- ***The device must perform reliably***
  During examination of the safety mechanism, the mechanism could be activated reliably in all instances. It was not possible to release the needle once more with exception of intentional disregard of the Instructions of Use.
- ***The safety mechanism must be an integral part of the safety device, not a separate accessory***
  The safety mechanism is attached to the holder. Due to the needle already being threaded onto the holder, the shield cannot be removed anymore. The pre-assembled combination therefore has an integrated safety mechanism.
- ***The device must be easy to use and require little change of technique on the part of the health professional***
  The assembly of both components and the activation of the safety mechanism should be trained at least once, as stated in the Instructions of Use. The implementation of the combined products for blood collection is not different to the usual process, therefore not requiring major changes to the known procedure.
- ***The activation of the safety mechanism must be convenient and allow the care-giver to maintain appropriate control over the procedure***
  The safety mechanism is always controlled by the user himself. The required force for activation of the safety mechanism is high enough to prevent accidental activation, but the user has to completely push the shield over the needle on his own after use.
- ***The device must not create other safety hazards or sources of blood exposure;***
  During examination, **VACUETTE® QUICKSHIELD Complete PLUS** did not create additional safety hazards.
- ***A single-handed or automatic activation is preferable***
  The shield of the **VACUETTE® QUICKSHIELD Complete PLUS Safety Tube Holder** can be pushed over the needle with one hand, either by using a free finger of the holding the holder/needle combination or by pressing it on a firm surface.

- ***The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual sign to the health professional***
  The activation can be heard.
- ***The safety mechanisms should not be easily reversible once activated***
  For longer needles (1,5") the safety mechanism could not be released again.
  The use of shorter needles (25 mm / 1") is problematic if the product is not immediately disposed and if the shield with the enclosed needle is intentionally and / or forcefully bent backwards by more than 130°, as the needle will then slip out of the safety mechanism and the contaminated sharp is exposed for possible needle-stick injuries once again. If the user disposes the used equipment immediately, the safety mechanism is sufficient in reducing the risk of needle-stick injuries until disposal since the user should not force the safety shield completely open during this short period of time.

4.4 TRBA 250

All requirements of TRBA 250 are met.

- ***[Safety equipment] must put neither patients nor workers at risk***
  The device can be used similar to normal blood collection equipment, therefore being no threat to either patient or user.
- ***[Safety equipment] must be easy to use and application-oriented***
  The usage is similar to usual equipment and can be easily adopted. The safety mechanism itself can be easily activated and does not hinder the procedure due to the possibility of repositioning of the shield. Training for safe handling should be required, to ensure right usage and disposal of the product.
- ***The safety mechanism is an integral part of the system and is compatible with other accessories***
  The safety mechanism is already attached to the holder. and held in place by the needle. The pre-assembled product therefore has an integrated safety mechanism.
- ***[The activation of the safety mechanism must] be self-triggering or allow single-handed operation***
  The shield of the **VACUETTE® QUICKSHIELD Complete PLUS Tube Holder** can be pushed manually over the needle with one hand, either by using a free finger of the holding the holder/needle combination or by pressing it on a firm surface.
- ***[The activation of the safety mechanism must] be possible immediately after use***
  The shield can be pushed over the needle immediately after the retraction of the needle.
- ***[The activation of the safety mechanism must] rule out subsequent use***
  The safety mechanism usually encapsulates the contaminated needle, especially the 1,5" needles. In case the user forcefully bends the safety shield open for 1" needles, subsequent use is almost impossible due to the bent needle.
- ***[The activation of the safety mechanism must] be indicated by a clear signal (tactile, visible or audible)***
  The locking of the safety mechanism can be heard.

5 Expert opinion

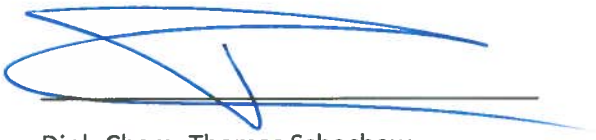
The products **VACUETTE® QUICKSHIELD Complete PLUS**, respectively all combinations of **VACUETTE® QUICKSHIELD Safety Tube Holder** and **VACUETTE® VISIO PLUS Needles,** by Greiner Bio-One GmbH are meeting the requirements set by Clause 6 of the Annex of the *European Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU,* Number 5 of the *Implementation Guidance for the EU Framework Agreement, Council Directive and Associated National Legislation* by the *European Biosafety Network* and Number 4.5.2 (4) 4 of the German *Technical Rule for Biological Agents (TRBA) 250.*
Therefore, the products are safety equipment with a safety-engineered mechanism appropriate to prevent needle-stick injuries for the process of blood collection.

If the product is used according to the instructions for use of the manufacturer, the product is deemed safe for the intended application and can thereby reduce the risk of needle stick injuries of healthcare works during blood collection and disposal of medical waste.

During the use of the product with shorter needles (25 mm or less) it is possible that an intentional misuse of the product could lead to the needle being exposed again. For the safe use of the product it is therefore essential for a user to follow the instructions for use of the manufacturer.

VPA Prüf- und Zertifizierungs GmbH

Remscheid, 20.06.2017



Dipl.-Chem. Thomas Schochow