

BD

Franklin Lakes, NJ
(888) 237-2762
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Hemco Corp

Independence, Mo
(816) 796-2900
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Kimberly-Clark Professional

Roswell, Ga
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1. What is the brand name of your company's safety product?	BD Vacutainer UltraTouch push-button blood collection set	MicroFlow III	Kimberly-Clark Purple Nitrile exam gloves
2. What year was the product first released to market?	2016	2016	1999
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations or certified compliance with voluntary standards.	CE mark, 2016; FDA 510(k), 2016.	n/a	FDA 510(k), 2010; FDA cleared for use in chemotherapy, 2017; tested for 29 drugs and 4 hormones per ASTM D6978-05, 2017; meets FDA USP 800 guidelines, 2016.
4. What is the intended use or primary function of the product?	A sterile, multiple sample, single-use blood collection set intended for venipuncture to obtain blood specimens from patients.	Class 1 ductless carbon-filtered workstation.	Barrier protection.
5. Who or what is the product designed to protect?	<input type="checkbox"/> Caregivers <input checked="" type="checkbox"/> Healthcare professionals <input type="checkbox"/> Laboratory equipment <input checked="" type="checkbox"/> Laboratory staff <input checked="" type="checkbox"/> Patients <input checked="" type="checkbox"/> Patient specimens <input type="checkbox"/> Test data	<input type="checkbox"/> Caregivers <input type="checkbox"/> Healthcare professionals <input checked="" type="checkbox"/> Laboratory equipment <input checked="" type="checkbox"/> Laboratory staff <input type="checkbox"/> Patients <input type="checkbox"/> Patient specimens <input type="checkbox"/> Test data	<input type="checkbox"/> Caregivers <input type="checkbox"/> Healthcare professionals <input type="checkbox"/> Laboratory equipment <input checked="" type="checkbox"/> Laboratory staff <input type="checkbox"/> Patients <input type="checkbox"/> Patient specimens <input type="checkbox"/> Test data
6. What kind of safety protection does the product provide?	<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Electrical <input type="checkbox"/> Environmental <input type="checkbox"/> Mechanical <input type="checkbox"/> Other	<input type="checkbox"/> Biological <input type="checkbox"/> Electrical <input checked="" type="checkbox"/> Environmental <input type="checkbox"/> Mechanical <input type="checkbox"/> Other	<input checked="" type="checkbox"/> Biological <input type="checkbox"/> Electrical <input checked="" type="checkbox"/> Environmental <input type="checkbox"/> Mechanical <input type="checkbox"/> Other
7. If you answered "other," explain briefly.			
8. By what mechanisms or modes of action does the product ensure safety protection?	The needle retracts after use.	Equipped with activated carbon filtration; suited for fumes, odors, and nonhazardous chemical vapors.	Barrier properties.
9. In what ways do the product's materials, components, or functional features contribute to the performance of its safety functions?	The single-handed, in-vein safety activation instantly retracts the needle after use, reducing accidental needlesticks by up to 88%.	Completely self-contained, with integral recessed work surface to contain spills.	Made of highly durable nitrile polymer to guard against incidental splash exposure; the material also provides excellent dexterity and comfort; textured fingertips enhance grip and beaded cuffs make donning easier.
10. What are the product's storage or maintenance requirements?	Keep away from sunlight.	Tabletop workstation; replace filters.	Store in a cool dry place; open box should be shielded from exposure to direct sunlight, intense artificial light, x-ray machines, and other sources of ozone.
11. What is the typical training time for the product?	Under 15 minutes.	n/a	<30 minutes.
12. What types of technical support are available?	A customer service line, online technical support, and direct sales/clinical support.	Maintenance manual, factory.	APEX training, a unique employee training program that facilitates the changeover to this product; 24-hour internet and telephone support also provided.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Engineered to minimize patient discomfort during blood collection; a specially designed needle reduces penetration forces and allows use of a smaller gauge size without compromising filling time or sample quality.	Fiberglass composite construction.	Recyclable through the RightCycle program; not made with natural rubber latex; well-known in the market.

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Oceasoft SA

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Thermo Fisher Scientific

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Vino Optics

Miami, Fla
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Kimtech A7 certified liquid barrier gown	Cobalt ML3	Thermo Scientific Samco Clicktainer vials	Oxy-Iso blood draw vein glasses
2017	2017	2017	2012
Meets FDA USP 800 guidelines, 2017; tested for permeation of chemotherapy drugs and hormones per ASTM F739-12, 2016.	n/a	CE mark, 2017; ISO BS EN 14254; ISO BS EN 14401; compliant with applicable FDA regulations.	ANSI Z87.1 impact standards
Liquid barrier protection to protect the worker and the environment against spills, splashes, and powders from hazardous drugs.	Wireless temperature data logger for transport of thermosensitive products.	Secure collection and handling of fluid, solid, and powder samples, including urine, sputum, and stool specimens.	Enhanced perception of veins by medical personnel interested primarily in blood draws.
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		n/a	
Barrier properties.	Automatically collects temperature data recorded by Cobalt ML3 modules and transfers the information to a secure Cloud platform; provides continuous temperature monitoring across the entire cold logistics chain.	Leakproof click-seal closure design.	Medical protective eyewear; safety to medical professionals and patients when inserting an IV and preventing multiple pricks.
Seamless front design to minimize the risks posed by working with hazardous drugs or liquids; enhanced protection via an impervious fabric, as tested per ASTM F739-12.	Features LoRaWAN, the LoRa Alliance's long-range communication protocol for connectivity performance; uses low-energy-consumption technologies; external waterproof, protective casing can be used for logistics and transport.	Rigorously 95 kPa pressure tested to ensure leakproof performance; click-seal system ensures correct cap closure the first time; provides both sample and user safety.	Blood visual-enhancement technology aids in the perception of veins and health signs.
n/a	0°C to 50°C (32°F to 122°F).	No storage requirements, product is fully stackable for ease of storage.	n/a
<30 minutes.	Less than 1 day.	Minimal training required; instructions for use flier is included in every case of product to explain how to use.	n/a
APEX training, a unique employee training program that facilitates the changeover to this type of apparel; video on how to don and doff garment; 24-hour internet and telephone support also provided.	Hotline; technical support; training; data sheet; user guides.	Full technical support is available from Thermo Fisher Scientific, 24 hours a day, 7 days a week.	Not required.
Impervious fabric; seamless front/closed back; easy don and doff design; thumb loops to maintain glove/garment interface; low lint; bulk packaged in a range of sizes to ensure comfort and compliance.	Developed in accordance with EN NF 12830 and 21 CFR Part 11 standards; easy to install and use; enables performance and long-range connectivity thanks to the LoRaWAN protocol, for temperature monitoring over the supply chain; provides data traceability and security and geolocation.	95 kPa pressure tested to ensure leakproof performance; unique click-seal system; wide range of products available.	Fully adjustable, comfort frames; anti-fog and anti-scratch coatings; UV-protective O2Amp technology enhances ability to detect vasculature and veins; complementary to other vein detection devices and uniquely suited for expeditionary use; no battery, no electricity, no wires; filtering properties can't be rubbed or scraped off.

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4. What is the intended use or primary function of the product?
5. Who or what is the product designed to protect?
6. What kind of safety protection does the product provide?
7. If you answered "other," explain briefly.
8. By what mechanisms or modes of action does the product ensure safety protection?
9. In what ways do the product's materials, components, or functional features contribute to the performance of its safety functions?
10. What are the product's storage or maintenance requirements?
11. What is the typical training time for the product?
12. What types of technical support are available?
13. What capabilities, features, or accessories distinguish this product from others on the market?

Vino Optics

Miami, Fla
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Oxy-Amp vein glasses	Hemo-Iso bruise-finding glasses
2012	2012
ANSI Z87.1 impact standards	ANSI Z87.1 impact standards
Amplifies perception of veins, oxygenation, pallor, cyanosis, rashes, and erythema; favored by paramedics; can be used as general purpose protective eyewear.	Enables early detection of bruising, pooling of blood, bedsores, and hematomas.
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Dual use: protective eyewear and vein-enhancement for EMT/paramedic use, as well as medical protective eyewear; safety to medical professionals and patients when inserting an IV and preventing multiple pricks.	Medical protective eyewear; safety to medical professionals and patients when inserting an IV and preventing multiple pricks.
Blood visual-enhancement technology aids in the perception of veins and health signs.	Blood visual-enhancement technology aids in the perception of veins and health signs.
n/a	n/a
n/a	n/a
Not required.	Not required.
Eyewear enhances vascular and clinical perception for sensing vasculature and its clinical implications; provides sun, UV, and impact protection; enhances perception of veins in daylight conditions; beneficial for pediatric applications.	Fully adjustable, comfort frames; anti-fog and anti-scratch coatings.

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UPCOMING TECH GUIDES

Each month, *CLP* invites IVD manufacturers and clinical laboratory suppliers to complete a standardized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future print issues of *CLP*.

January/February

Lab and point-of-care glucose monitors

March

Laboratory software and information technologies

April/May

Microbiology systems and tools

June

Anatomic and digital pathology instruments and tools

Urinalysis assays and instruments

To be considered for inclusion, contact associate editor Elaine Sanchez Wilson at ewilson@medqor.com.

