

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


 greiner bio-one

QUALITY CONTROL CERTIFICATE

Customer: MEDIATECH SYSTEMS SRL
Delivery No.: 7200149319

Order No.	Product description	Item No.	Lot No.	Expiry date	Quantity	Sterility	Inspections carried out and passed
2015 - 04 / 11 X	VACUETTE® Multiple Use Drawing Needle 18G x 1 1/2" pink, sterile, latex-free, for veterinary use only 1.25 x 38 mm	450048	15E08A	2020-04	24.000 PC	sterile	visual physical chemical
2015 - 04 / 11	Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450066	15E15	2018-04	2.000 PC	sterile	visual physical chemical
2015 - 04 / 11	VACUETTE® Luer Adapter 20G sterile, latex-free	450070	15F10A	2020-05	96.000 PC	sterile	visual physical chemical
2015 - 04 / 11	VACUETTE® Multiple Use Drawing Needle 22G x 1" black, sterile, latex-free 0.7 x 25 mm	450071	15F10A	2020-05	6.000 PC	sterile	visual physical chemical
2015 - 04 / 11	Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450089	15C07	2018-02	4.000 PC	sterile	visual physical chemical

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Our products meet the following regulations and standards as far as applicable to the individual product:

- Directive 98/79/EC of the European Parliament and of the Council of 27th Oct 1998 on in vitro diagnostic medical devices
- Council Directive 93/42/EEC of the 14th June 1993 concerning medical devices
- ISO 9001 "Quality management systems - Requirements"
- EN ISO 13485 "Medical devices - Quality management systems - Requirements for regulatory purposes"
- EN ISO 14971 "Medical devices - Application of risk management to medical devices"
- ISO 11135 "Sterilization of health care products - Ethylene oxide"
- EN ISO 15223 "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied"
- EN 980 "Symbols for use in the labelling of medical devices"
- ISO 6710 "Single-use containers for venous blood specimen collection"
- ISO 8655 "Piston-operated volumetric apparatus"
- EN 14254 "In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans"
- EN 14820 "Single-use containers for human venous blood specimen collection"
- ISO 11137 "Sterilization of health care products - Radiation"

This certificate is valid only for the products listed above which are part of this shipment.

28. SEP. 2015

Date



A. A. Vassallo Guada
Andreas Aichinger
Quality Manager