



Kontrollblutherstellungs-  
und Vertriebs GmbH

## Technical Datasheet

<u>PRODUCT</u>	
Product Name:	A-K-FIX Blood Sampler for Blood Gas sterile with Cone Cap
Product classification:	In vitro Diagnostic Medical Device covered by Art. 9, Paragraph 1 Sentence 1 of the Directive 98/79/EC
REF:	191202
Intended use:	Single-use Blood Sampler for pH/blood gas, electrolyte, oximetry and metabolite analysis
Connector:	Luer Slip
Sampling volume:	> 230 µl (232 µl – 251 µl)
Preparation of the product:	~100 I.U./ml Lithium-Heparin (balanced)
Shelf life:	3 years
Packaging:	Single packed, sterile, 50 pieces per box, 20 boxes per carton
Material of primary packaging:	Sterile paper MM 70-1 Film PE 62-1
Storage temperature:	2-30 °C

<u>COMPONENT / MATERIALS LIST</u>	
<u>Device component</u>	<u>Material</u>
Closing Cap	Polyethylene
Luer Connector	Polypropylene
Capillary	Unplasticized amorphous thermoplastic with medical compliance
Autostop-End-Cap	Polyethylene
Autostop-Filter	Porous Polyethylene

<u>BASIC PRODUCT CHARACTERISTICS</u>
Highly transparent capillary
Self-sealing Autostop-Cap
Fixed sample volume
Universally use due to standard Luer Connector
Unbreakable, maximum safety for user and patient

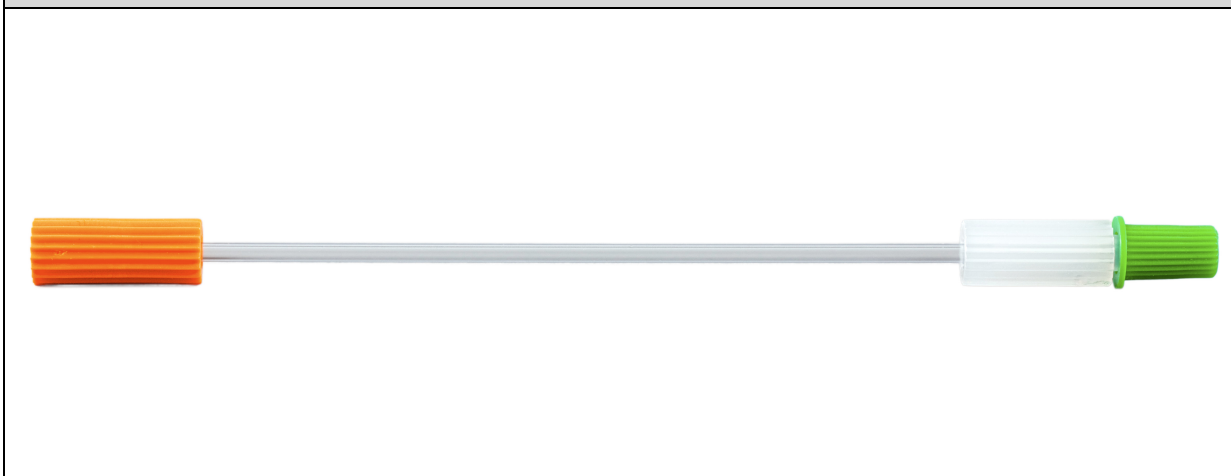


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### STERILIZATION

Type:	EO-Gas
<p>This confirms that the above product has been sterilized with EO-Gas and has been certificated as sterile. This is in accordance with procedures outlined in DIN EN ISO 11135:2014:</p> <p>Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.</p>	

### PRODUCT PICTURE



We hereby certify that the products were produced under a quality system following the standard EN ISO 13485:2016 + AC:2016 and the Directive 98/79/EC is fulfilled.



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