



Kontrollblutherstellungs-
und Vertriebs GmbH

Technical Datasheet

<u>PRODUCT</u>	
Product Name:	Capillary Blood Collection System
Product classification:	In vitro Diagnostic Medical Device, covered by Art. 2, Sentence 3 of the Regulation (EU) 2017/746 as class A according to Rule 5c Annex VIII Regulation (EU) 2017/746
REF:	650715
Intended use:	Prepared sample container with end-to-end plastic capillary for the collection, storage and dispensing of blood samples from the human body for subsequent in vitro diagnostic haematological analyses
Length:	40 mm + 1 mm
Sampling volume of capillary:	>75 µl (75 µl – 82 µl)
Sampling volume of vessel:	Max. 500 µl
Preparation of the product:	EDTA-K3 – concentration: 1-2 mg per 1ml blood sample
Colour code:	Pink
Shelf life:	3 years
Packaging:	Non-sterile; 50 pieces per polybag, 70 bags per carton
Material of primary packaging:	Polyethylene
Storage temperature:	2-30 °C

<u>COMPONENT / MATERIALS LIST</u>	
<u>Device component</u>	<u>Material</u>
Capillary	Unplasticized amorphous thermoplastic with medical compliance
Vessel	Polypropylene
Closing Cap	Polyethylene

<u>BASIC PRODUCT CHARACTERISTICS</u>
Highly transparent capillary
Fixed sample volume
Unbreakable, maximum safety for user and patient
Safe handling during the whole sampling process



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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 Regulation (EU) 2017/746 is fulfilled.



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