

Kremsmünster, 09/05/2019

## VACUETTE® Blood Collection System – Product Data Specifications

<b>Item N°<sup>1</sup></b>	455007								
<b>Characterisation<sup>1,2</sup></b>	Z Urine No Additive Urine Collection Tube with Safety Cap, non-ridged								
<b>Description<sup>1</sup></b>	<table> <tr> <td><i>Dimension</i></td> <td>16x100mm</td> </tr> <tr> <td><i>Capacity</i></td> <td>10ml</td> </tr> </table>	<i>Dimension</i>	16x100mm	<i>Capacity</i>	10ml				
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<b>Materials<sup>1,3</sup></b>	<table> <tr> <td><i>Tube</i></td> <td>PET</td> </tr> <tr> <td><i>Label</i></td> <td>paper label</td> </tr> <tr> <td><i>Cap</i></td> <td>PE yellow</td> </tr> <tr> <td><i>Ring</i></td> <td>PP yellow</td> </tr> </table> <i>Rubber stopper</i> Bromobutyl rubber, non-latex	<i>Tube</i>	PET	<i>Label</i>	paper label	<i>Cap</i>	PE yellow	<i>Ring</i>	PP yellow
<i>Tube</i>	PET								
<i>Label</i>	paper label								
<i>Cap</i>	PE yellow								
<i>Ring</i>	PP yellow								
<b>Additive<sup>1,3</sup></b>	No additive								
<b>Manufacturer<sup>2</sup></b>	Greiner Bio-One GmbH Bad Haller Str. 32 A-4550 Kremsmünster								
<b>Sterilisation<sup>1</sup></b>	Sterile interior: SAL 10 <sup>-6</sup> (SAL = Sterility Assurance Level) Standard: ISO 11137								
<b>Directive<sup>2</sup></b>	IVDD 98/79/EC “Directive 98/79/EC of the European Parliament and council of 27th of October 1998 on in vitro diagnostic medical devices” Classification: Other device (all devices except Annex II and self-testing devices).								
<b>Storage<sup>1</sup></b>	4-25°C								
<b>Shelf Life</b>	473 days								
<b>Packaging<sup>1</sup></b>	50 tubes per tray (Material: Polystyrene) Trays wrapped in a transparent foil (Material: Polyethylene) 24 trays per case = 1200 tubes								

## Sources:

- 1 Label Master Data AT\_VAC\_LMDS\_455007\_Rev13
- 2 CE list
- 3 DMR
- 4 Instruction for use 980205\_Rev09

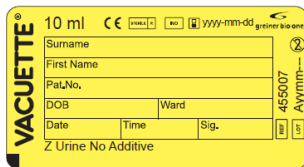
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### Label information<sup>4</sup>

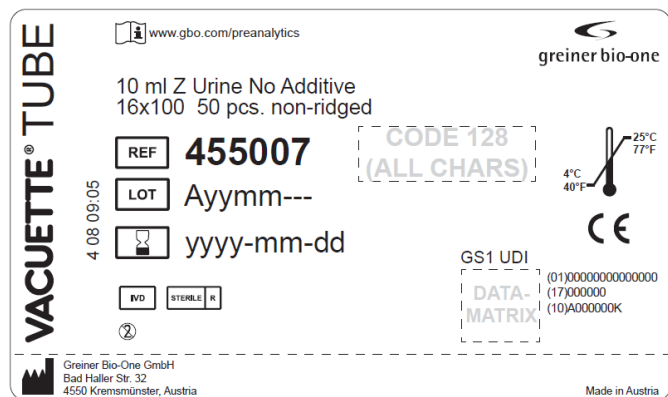
	Manufacturer		Temperature limit
	Use-by date		Consult instructions for use
	Batch code		Sterilized using irradiation
	Catalogue number		Sterilized using ethylene oxide
	Do not re-use		

### Labelling<sup>1</sup> Tube-Rack-Carton – Examples

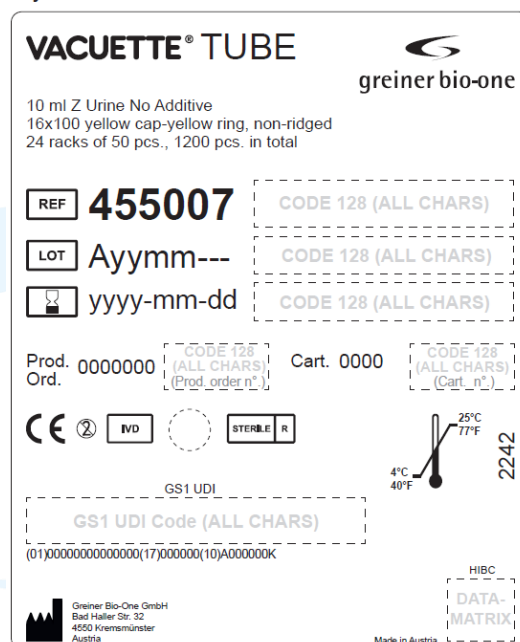
Layout Tube Label:



Layout Rack Label:



Layout Carton Label:



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