
 <b>greiner bio-one</b> Page 6 / 10	<b>DEVICE MASTER RECORD</b>	 <b>greiner bio-one</b> A AN_QMI_0403_01_03 Rev00
	<b>VACUETTE® EDTA Blood Collection Tubes</b>	
	GREINER Bio-One GmbH, Bad Haller Straße 32, 4550 Kremsmünster, Austria	

### 3. Product Requirements

<b>3.1. Product Standards</b>	01_List of applied standards VACUETTE® Blood Collection Tubes Responsibility: Head of Quality Management
<b>3.2. Sterilization</b>	<input checked="" type="checkbox"/> sterile (SAL 10 <sup>-6</sup> ) <input type="checkbox"/> aseptic <input type="checkbox"/> non-sterile / not sterilized <input type="checkbox"/> sterilized (SAL lower than 10 <sup>-6</sup> ); specify SAL: ..... Sterilization Method: <input checked="" type="checkbox"/> E-Beam <input checked="" type="checkbox"/> Gamma <input type="checkbox"/> ETO <input type="checkbox"/> Other (specify): ..... Responsibility: Head of Quality Management
<b>3.3. Chemistry</b>	Chemicals in accordance with the ISO 6710 / EN 14820 Responsibility: Head of Quality Management
<b>3.4. Microbiology</b>	No additional, special requirements Responsibility: Head of Quality Management

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