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

3. Product Requirements

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

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