


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p>UKAS TESTING</p> <p>21701</p> <p>Accredited to ISO/IEC 17025:2017</p>	<p>Smithers MDT Limited</p> <p>Issue No: 006 Issue date: 29 August 2024</p>	
	<p>Shawbury Shrewsbury Shropshire SY4 4NR</p>	<p>Contact: Richard Barlow Tel: +44 (0)1939 250383 E-Mail: rbarlow@smithers.com Website: www.smithers.com</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
MEDICAL DEVICE TESTING		
Vials	Container closure seal integrity	BS EN ISO 8871-5:2016 (Annex D)
Pre-Filled Syringes	Breakloose and glide force	BS ISO 11040-4:2015 (Annex E) BS ISO 11040-8:2016
	Dye solution tightness test	BS ISO 11040-4:2015 + A1:2020 (Annex H)
Needle based injection systems	Dose accuracy	BS EN ISO 11608-1:2015 BS EN ISO 11608-1:2022
Syringes	Plunger operation force	BS EN ISO 7886-1:2018 (Annex E) BS EN ISO 7886-1:1997 (Annex G)
Small bore connectors	Fluid Leakage	ISO 80369-7:2021 and ISO 80369-20:2015
	Sub-atmospheric pressure air leakage	ISO 80369-7:2021 and ISO 80369-20:2015
	Stress cracking	ISO 80369-7:2021 and ISO 80369-20:2015
	Resistance to separation (axial load or unscrewing)	ISO 80369-7:2021 and ISO 80369-20:2015
	Resistance to Overriding	ISO 80369-7:2021 and ISO 80369-20:2015
	Disconnection by unscrewing	ISO 80369-20:2015
	Modification of test methods to generate variable data	ISO 80369-20:2015
<p>END</p>		