


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |   |
|---|---|---|
|  <p>Accredited to<br/>ISO/IEC 17025:2005</p> | <b>Medical Engineering Technologies Ltd</b><br><br><b>Issue No: 007 Issue date: 05 July 2018</b>    |   |
|   | <b>Unit 16</b><br><b>Holmstone Road</b><br><b>Dover</b><br><b>CT17 0UF</b><br><b>United Kingdom</b> | <b>Contact: Mr Mark Turner</b><br><b>Tel: +44(0)8454 588924</b><br><b>E-Mail: m.turner@met.uk.com</b><br><b>Website: www.met.uk.com</b> |
| <b>Testing performed at the above address only</b>  |   |   |

### DETAIL OF ACCREDITATION

| Materials/Products tested           | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used  |
|-------------------------------------|---|---|
| MEDICAL PACKAGING                   | Requirements for materials, sterile barrier systems and packaging systems for the following tests | BS EN ISO 11607:Part1:2009  |
|                                     | Accelerated ageing  | ASTM F1980-16   |
|                                     | Visual Inspection for flaws and channels in seals   | ASTM F1886<br>ASTM F1886M -2016   |
|                                     | Seal Strength test by rupture pressure  | ASTM F1140/F1140M-13-<br>ASTM F2054-13  |
|                                     | Seal Integrity test by dye penetration  | ASTM F1929-15   |
|                                     | Seal strength by peel force   | BS EN 868-5:2009  |
|                                     | Trace gas integrity testing using hydrogen  | IHM WI 24 May 2013  |
|                                     | Needle based injection systems for medical use  | BS EN ISO 11608-1:2015<br>Excluding clauses:<br>10.9 – Vibration testing<br>10.10 – Electromagnetic Compatibility (EMC) |
|                                     | Air transport simulation  | IHM WI 54 June 2017   |
|                                     | Break loose & Glide force   | IHM WI 52 July 2017   |
|                                     | Cartridge removal force – Axial load  | IHM WI 58 July 2017   |
| Cartridge removal force – Side load | IHM WI 59 July 2017   |   |
| Needle cap removal force            | IHM WI 52 July 2017   |   |



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| MEDICAL PACKAGING<br>(cont'd) | Needle based injection systems for medical use<br>(cont'd)<br><br>Leak test   | BS EN ISO 11608-1:2015<br>Excluding clauses:<br>10.9 – Vibration testing<br>10.10 – Electromagnetic Compatibility (EMC)<br><br>IHM WI 57 July 2017  |
| MEDICAL PACKAGING             | Shipping Containers and systems sequential performance tests<br><br>Testing of Packages for Single Parcel Delivery Systems<br><br>Partial Simulation Performance Test for Packaged-Products 68kg (150lbs) or Less<br><br>Conditioning Containers, Packages, or Packaging Components for Testing<br><br>Max Temperature +60°C<br>Min Temperature -30°C<br>Relative Humidity 15 to 90%<br><br>Drop test of loaded containers by free fall<br><br>Concentrated Impacts to Transport Packages | ASTM D4169-16<br>Excluding: -<br>14 Schedule G -Simulated Rail Switching<br>15 Schedule H – Environmental Hazard<br>16 Schedule I – Low Pressure (High Altitude) Hazard<br><br>ASTM D7386 – 16<br>Excluding:-<br>12 Schedule I Bridge Impact<br>13 Schedule J Hazard drop<br>14 Schedule K – High Altitude<br>16 Tip Over Test (D6179)<br>17 Rotational Edge Drop Test (D6179)<br><br>ISTA 2A-2011<br><br>ASTM D4332-14<br><br>ASTM D5276-98(2017)<br><br>ASTM D6344 - 04(2017) |



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| MEDICAL PACKAGING<br>(cont'd) | Random Vibration Testing of Shipping Containers<br><br>Environmental testing - Vibration (sinusoidal)<br><br>Environmental testing - Shock<br><br>Vibration Test Parameters<br>Max Payload 300kg<br>Max acceleration 100g<br>Frequency Range 2-2000Hz<br>Displacement 51mm (p-p)<br>Max velocity 1.8m/s<br>Peak Force 600kgf<br>Vertical only at ambient<br>Classical Shock pulses half-sine, sawtooth and trapezoidal<br><br>Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads<br><br>Up to 2549kgf | ASTM D4728-17<br>ASTM D999-08(2015) – Method A1 only<br><br>BS EN 60068-2-6:2007<br><br>BS EN 60068-2-27:2007<br><br><br><br><br><br><br><br><br><br><br>ASTM D642-15 |

END