

**Specimen receptacles, non-evacuated****Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices.**

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

<b>General Product Names:</b>	Specimen receptacles, non-evacuated
<b>Legal Manufacturer:</b>	International Scientific Supplies Ltd., Unit 6, Valley Road, Bradford, BD1 4RU, West Yorkshire, England
<b>SRN:</b>	Not yet available
<b>Basic UDI-DI:</b>	506047475A99CP
<b>Variants:</b>	See Appendix II
<b>Intended Use:</b>	Specimen receptacle for the collection of samples for laboratory analysis
<b>IVR Classification:</b>	Class A (rule 5 of EU IVD Regulation 2017/746 Annex VIII)
<b>Notified Body:</b>	N/A
<b>CE Certificate Reference:</b>	N/A
<b>IVD Directive Assessment route:</b>	Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar BKR 4013 Malta
<b>EU Authorised Representative SRN:</b>	MT-AR-000000234
<b>Applied Standards:</b>	See Appendix I
<b>EMDN code:</b>	A99

**Name:** Andrew Littlewood**Position:** Managing Director**Signed:****Date:** 01 Mar 2023**Place:** Bradford



## Appendix I – Applicable Standards

This declaration is also in conformity with the following European standards and Common Specifications:

<b>2017/746</b>	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
<b>EN ISO 13485:2016 +A11:2021</b>	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
<b>BS EN ISO 9001:2015</b>	Quality Management Certification
<b>EN ISO 18113-1:2022</b>	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
<b>EN ISO 14971:2019</b>	Medical Devices – Application of Risk Management to Medical Devices
<b>EN ISO 6710:2017</b>	Single use containers for human venous blood specimen collection
<b>EN ISO 15223-1:2021</b>	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
<b>EN ISO 20417:2021</b>	Medical devices. Information to be supplied by the manufacturer.
<b>BS EN 14254:2004</b>	In vitro diagnostic medical devices. Single-use receptacles for the collection of specimens, other than blood, from humans

**Appendix II – Product Listing**

Family	Version	UDI-DI	REF
Plastic Universal Containers	30ml Polystyrene Universal Unlabelled	506047475552	UNI0002
Plastic Universal Containers	30ml Polystyrene Universal Unlabelled, Gamma Irradiated	506047475620	UNI0010
Plastic Universal Containers	30ml Polystyrene Universal Red Cap No Label Gamma Irradiated	506047475621	UNI0025
Plastic Universal Containers	30ml Polystyrene Universal, Patient Label	506047475553	UNI0003
Plastic Universal Containers	30ml Polystyrene Universal Patient Detail Label Gamma Irradiated	506047475081	UNI0003IR
Plastic Universal Containers	30ml Clarified Polypropylene Universal with Spoon, No Label	506047475622	UNI0033
Plastic Universal Containers	30ml Clarified Polypropylene Universal Labelled with Spoon	506047475560	UNI0039B
Specimen Containers	100ml Polystyrene Container Metal Cap Unlabelled	506047475417	SC1002
Specimen Containers	250ml Polystyrene Container Metal Cap Unlabelled	506047475420	SC2502
Specimen Containers	60ml Clarified Polypropylene Container Metal Cap Unlabelled	506047475428	SC6029
Specimen Containers	150ml Container Metal Cap Unlabelled	506047475433	SCS1502
Specimen Jars	350ml Polystyrene Screw Cap Jar Non-Sterile Unlabelled	506047475452	SCJ028