International Scientific Supplies Ltd

Declaration of Conformity

Version: 2.0
Date: 01 Mar 2023

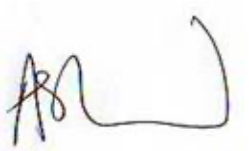
Specimen receptacles, non-evacuated

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.

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

Name: Andrew Littlewood **Position:** Managing Director



Signed: **Date:** 01 Mar 2023 **Place:** Bradford

International Scientific Supplies Limited
Unit 6, Valley Road, Bradford, BD1 4RU, West Yorkshire, United Kingdom
Tel:01274720070 Fax:01274728295 Email: sales@intscientific.com Web: www.intscientific.com
Company Registered No. 4373041 VAT Reg No. GB790146918

Appendix I – Applicable Standards

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

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

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