UKCA Declaration of Conformity

To Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

epredia
Enhancing precision cancer diagnostics

UK CA

Legal Manufacturer's Name: Richard Allan Scientific LLC, a subsidiary of Epredia
Legal Manufacturer's Address: 4481 Campus Drive, Kalamazoo, Michigan 49008 USA

Richard Allan Scientific LLC, a subsidiary of Epredia declares that the In Vitro Diagnostic Medical Devices listed in the following pages are in conformity with all applicable provisions of the following UK Statutory Instruments and their amendments, and therefore entitled to bear the UKCA Mark:

☐ Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), including European Union (Withdrawal) Act 2018, for REACH compliance

Product Trade Name, product catalogue number, photograph (optional)	Mounting Media
Product Description	See Appendix 1
Intended Purpose	For in vitro diagnostic use. For use as a permanent, resin-based mounting medium in histological and cytological preparations.
UK Responsible Person Name and Address:	Shandon Diagnostics Limited, a subsidiary of Epredia, Tudor Road, Manor Park, Runcorn, Cheshire, WA7 1TA, UK
Conformity Assessment Route	Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), Part IV In Vitro Diagnostic Medical Devices
Classification	General IVD
Nomenclature (GMDN)	43550, Microscopy mounting medium IVD 59122, Xylene solution substitute IVD
Date of UKCA Marking	5th January 2023

We hereby declare under our sole responsibility that these products conform with the relevant provisions of the UK MDR 2002.

Richard Allan Scientific LLC, a subsidiary of Epredia confirms that the products listed are manufactured under a controlled and approved Quality Management System that maintains a post market surveillance and vigilance procedure. This Declaration of Conformity is issued under the sole responsibility of Richard Allan Scientific LLC, a subsidiary of Epredia.

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Approved by: Sophie Love

Sophie Love
Manager, Regulatory Affairs

Place of Issue: Runcorn, UK

Date of Issue: 09-FEB-2023.

Revision: 01

- **Appendix 1 – Device Information:**

Product Number	Product Name	GMDN
4211	ClearVue ™ Mountant	43550
4212	ClearVue ™ XYL Mountant	43550
1900331	Shandon-Mount™	43550
1900333	Shandon-Mount™	43550
9990435	Shandon-Mount™	43550
9990402	Immu-Mount™	43550
9990412	Immu-Mount™	43550
9990414	Immu-Mount™	43550
9999120	EZ-Mount™	43550
6769007	Synthetic Mountant	43550
9990440	Consul-Mount (Histology)	43550
9990441	Consul-Mount (Cytology)	43550
4111	Mounting Medium	43550
4112	Mounting Medium	43550
8310-4	Cytoseal™ 60	43550
8310-16	Cytoseal™ 60	43550
8311-4	Cytoseal™ 280	43550
8312-4	Cytoseal™ XYL	43550
8312-16E	Cytoseal™ XYL	43550
TA-125-AM	Aqua-Mount	43550
13800	Lerner Labratories Aqua-Mount	43550
1900231	Xylene Substitute	59122
1900233	Xylene Substitute	59122
9999122	Xylene Substitute	59122

Document Approvals

Approved Date: 22 Feb 2023

Approval Task Verdict: Approve	Sophie Love, Regulatory Affairs Specialist III (sophie.love@epredia.com) Regulatory Approval 22-Feb-2023 11:24:12 GMT+0000

QA Approval Task Verdict: Approve	Derya Yakar, Quality Engineer (derya.yakar@epredia.com) Quality Assurance Approval 22-Feb-2023 12:54:36 GMT+0000