# Declaration of Conformity

*This Declaration of Conformity, issued under the sole responsibility of the manufacturer, is only valid when the IVD is used in accordance with the instructions for use*

**Manufacturer:** Richard-Allan Scientific LLC, a subsidiary of Epredia, 4481 Campus Drive, Kalamazoo, Michigan 49008 USA

**Brand Name**: Epredia

**Authorized Representative:** Epredia Netherlands B.V., Essendonk 30, 4824 DA Breda, Netherlands

**Notified Body:** N/A, Self-Declared

**Risk Class:** These products are self-declared for compliance to Annex III of the IVDD. These products do not claim any analytes listed in Annex II List A or B and are not intended for self-testing.

| Catalog Number | Product Name | UDI-DI (GTIN) Code | EDMA Classification | GMDN Code |
|---|---|---|---|---|
| TA-135-HBL<br>TA-135-HBM<br>TA-135-HBH | HIER Buffer L<br>HIER Buffer M<br>HIER Buffer H | 0673693564410<br>0673693564427<br>0673693564458 | 13.07.01.90 | 57767 |
| **Intended purpose:** | For in vitro diagnostic use. For use in heat induced epitope retrieval in Immunohistochemistry | | | |
| **Product Common Name:** | HIER Buffer L, HIER Buffer M, HIER Buffer H | | | |
| **Year of CE Marking:** | 2007 | | | |

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|---|---|
| In Vitro Diagnostic Directive: | 98/79/EC in accordance with Annex III (Section 6 Excluded) and ISO 13485 Quality Assurance System (Full) |
| Certificate of REACH Compliance: | Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) |

Digitally signed by Plămădeală Inga
Date: 2021.12.22 14:08:15 EET
Reason: MoldSign Signature
Location: Moldova

Issued by: Qin Sun, International Regulatory Director

Date: 31-August-2020

Issue no: 1