



T E C H N O P A T H

## DECLARATION OF CONFORMITY



### Manufacturer

Techno-path Manufacturing Ltd.  
Fort Henry Business Park,  
Ballina,  
Co. Tipperary,  
Ireland

Product(s):

| Product Name      | Category          | Catalogue Number |
|-------------------|-------------------|------------------|
| Multichem IA Plus | Assayed/tri-level | 08P86-10         |

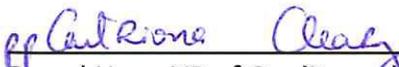
|                            |   |
|----------------------------|---|
| GMDN:                      | 47869   |
| Classification:            | Annex II List B                                 |
| Conformity Route:          | Annex IV  |
| Quality Management System: | EN ISO 13485:2016                               |
| QMS/CE Certification No.:  | V11038520001                                    |
| Issued By:                 | TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany |

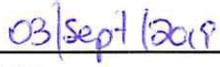
Notified Body Number: 0123

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

**Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.**

Signed for and on behalf of Techno-path Manufacturing Ltd.,

  
Bernd Hass, VP of Quality and Regulatory Affairs  
Techno-path Manufacturing Ltd.

  
Date





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## STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

| Standard                | Title  |
|-------------------------|--|
| EN ISO15223-1:2016      | Symbols to be used with medical device labels, labelling and information to be supplied.   |
| EN ISO13485:2016        | Medical devices – Quality management systems – Requirements for regulatory purposes  |
| EN 13612:2002 + AC:2002 | Performance evaluation of in vitro diagnostic medical devices  |
| EN 13641:2002           | Elimination or reduction of risk of infection related to in vitro diagnostic reagents  |
| EN 13975:2003           | Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – statistical aspects   |
| EN ISO 14971:2012       | Medical devices – Application of risk management to medical devices  |
| EN ISO 18113-1:2011     | In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements       |
| EN ISO 18113-2:2011     | In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use |
| EN 23640:2015           | In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents  |
| SOR/98-282, May 7, 1998 | Canada Medical Device Regulations  |

