



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):

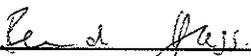
Product Name	Catalogue Number
Multichem S Plus Assayed	08P88-10/11/12
Multichem S Plus Unassayed	08P87-10/11/12

GMDN: 47869  
Conformity Route: Annex III Self-Declared  
Quality Management System: EN ISO 13485:2012 / ISO 13485:2003  
QMS Certification No.: LRQ 4008261/A  
Issued By: Lloyd's Register LRQA, 71 Fenchurch Street,  
London EC3M 4BS United Kingdom.

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.,

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

10-April-2017  
Date



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

Standard	Title
EN 980:2008 & ISO15223-1:2012	Symbols for use in the labelling of medical devices & Symbols to be used with medical device labels, labelling and information to be supplied.
ISO 13485:2012 + AC:2012	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 13640:2002 & EN23640:2013	Stability Testing of In vitro diagnostic reagents, & Evaluation of Stability of In vitro Diagnostic Reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations