TECHNOPATH

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.,

Bernd Hass

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 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