



**TECHNOPATH**  
CLINICAL DIAGNOSTICS

## DECLARATION OF CONFORMITY



### Manufacturer

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

Product(s):

Product Name	Category	Catalogue Number
Multichem A1c	Assayed/bi-level	04V0610

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2022

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.**

**I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 (Day) 01 (Month) 20 (Year)**

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

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

Ballina, Co. Tipperary 31-01-20  
Place and Date of Issue

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

<b>Standard</b>	<b>Title</b>
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 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