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
TECHNOPATH Multi-CHECK Cardiac Tri-Level	Assayed	CC510A / 944-512
TECHNOPATH Multi-CHECK Cardiac Level 1	Assayed	CC511A / 944-513
TECHNOPATH Multi-CHECK Cardiac Level 2	Assayed	CC512A / 944-514
TECHNOPATH Multi-CHECK Cardiac Level 3	Assayed	CC513A / 944-515

Intended Purpose:
For in vitro diagnostic use. For use with the AQT90 FLEX analyzer as an assayed liquid quality control (LQC) serum to monitor the precision of laboratory testing procedures for the parameters listed in the Specifications insert.

SRN	IE-MF-000001822
Basic UDI	539152344IMMA089Q
GMDN	Multiple clinical chemistry analyte IVD, control; 47869
EMDN	Immunochemistry (Immunology), W0102; Controls / Standards / Calibrators Immunochemistry, W010215. Cardiac Marker Controls, W0102152004
Conformity Route	Annex IX
Risk Class	Class C, Near Patient
Quality Management System	EN ISO 13485:2016
QMS Certificate No and Rev	V10 103852 0007 Rev 00
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	04-08-2027
Notified Body Number:	0123

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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 Regulation EU/2017/746.

This EU declaration of conformity is issued under the sole responsibility of Techno-path Manufacturing Ltd.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 13 **(Day)** 09 **(Month)** 22 **(Year)**

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

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

Ballina, Co. Tipperary 13- Sept - 2022
Place and Date of Issue

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDR EU/2017/746

Standard	Title
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices EN 13612:2002/AC:2002
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
ISO 14971:2019	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 (ISO 18113-1:2009)
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 (ISO 18113-2:2009)
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)