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Public Declaration IVDR Compliance

Public Declaration of conformity with EU regulation 2017/746 on in vitro diagnostic medical devices (IVD) HSE Mid West Pathology Services at University Hospital Limerick & Raheen TB Service, Ennis Hospital and Nenagh Hospital

IVDR Risk Classification Key:
Class A: Devices with a low risk to individual and public health. Examples include basic laboratory equipment and specimen receptacles.
Class B: Devices that pose a moderate risk to the individual but a low risk to public health.
Class C: Devices with a high risk to the individual and a moderate risk to public health.
Class D: Devices with the highest risk, posing a high risk to both individual and public health.

Organisation: *HSE*_ HSE Mid West Pathology Laboratories	**List of products ('in-house' devices) and documentation references.**	**Documentation references**
Contact Address: **University Hospital Limerick,** **St. Nessan's Road,** **Dooradoyle, Limerick, V94 F858** **Tel: 061 482756**	**Products which do not bear the CE mark.** 1. **Risk Class C: Microimmun Mumps IgM** Manufactured & Distributed by Clin-Tech Limited, Unit G Perram Works, Merrow Lane, Guildford, GU4 7BN, UK for detection of mumps virus specific IgM in human oral fluid, serum and plasma samples. **Justification for use:** The Microimmun commercial kit is the best available assay for this patient population, with high sensitivity and specificity (92.6% and 100%) Vs other currently available CE marked kits. The kit was previously CE marked prior to Brexit with no subsequent modifications because of not retaining CE marking post Brexit. **2. Risk Class C: CMV Immunohistochemistry Antibody.** **Justification for use:** CE Antibody unavailable; Satisfactory performance record; Clinical & Laboratory Consultant satisfaction. 3. **Risk Class A: Perls Prussian Blue Stain** Perls Prussian Blue Stain - Commercial control material unavailable; Satisfactory performance record; Laboratory Consultant satisfaction. **4. Risk Class A: Zeptometrix 3rd Party Controls:** • Zeptometrix NATtrol Respiratory panel 2.1 (NATRPC2.1-BIO)-	**Relevant Laboratory documentation reference.** 1. VF-L-SER-MUMPSM 2. VF-L-HIS-ANTIOPTVALCMV 3. VF-L-HAE-VALS-PPB 4. Zeptometrix 3rd party Controls • VF-L-SER-BIOFIRE-RP2.1PLUS • VF-L-MIC-ENTERICBIOGASTROPANEL2 • VF-L-MIC-ZEPTOFAECESCONTROLS • VF-L-MIC-EBCPE • VF-L-MIC-FILMARRAYME • VF-L-MIC-TVC5800

	Positive control used on the Biomerieux Biofire Film Array TORCH. • Zeptometrix NATtrol Carba R Verification panel NATCRVP-C - Positive control used as 3rd party IQC Entericbio CPE assay. • Zeptometrix NATtrol Gastro Panel 2 - Positive control used as 3rd party IQC Entericbio Gastro panel 2 assay. • Zeptometrix NATtrol MENINGIT ENCEPHALITIS BIOFIRE FILM ARRAY - Positive control used as 3rd party IQC. • Zeptometrix NATtrol BCID2 NATBCP2-BIO BIOFIRE FILM ARRAY BCID2 assay - Positive control used as 3rd party IQC. • Zeptometrix NATtrol MCNG T vaginalis/M. genitalium for Cobas 5800 - Positive control used as 3rd party IQC. **Justification for use of non-CE marked 3rd party IQC:** Adjunct IQC only (manufacturers IVDR controls in use also), not used for primary diagnostic decisions. CE mark process is in progress with Zeptometrix.	
Declaration:	*The following declaration encompasses all HSE Mid-West Laboratory site locations at; University Hospital Limerick, University Hospital Ennis, University Hospital Nenagh and the Public Health Laboratory, Raheen (TB service). For a list of currently accredited activity in the HSE Mid-West please visit www.INAB.ie ref; 303MT and 209MT. A list of accredited activities conducted under flexible scope is available on request. The entire testing repertoire offered by the HSE Mid-West Pathology service is available online here, under the Laboratory User Manual (ref; MP-A-GEN-USERMAN). This public declaration is published online with the Laboratory user manual ref; MP-A-GEN-USERMAN and other guidance documents.* ***Declaration:** HSE Mid-West Pathology Laboratories declares that the devices or products listed above are used only for their intended purpose and meet the general safety and performance requirements (GSPR) as set out in Annex I of Regulation 2017/746. All 'in-house' devices are verified to meet the requirements of ISO15189 regardless of test accreditation status and are assessed to ensure they meet the requirements of our patient population within that framework.*	
Date of Declaration:	**1st October 2025**	
Approved by:	**Ms Maria Hayes (MS046187), Pathology Quality Manager** **Ms Marie Carr (MS041790), Laboratory Manager**	
Next Review Date:	**October 2026**	