



Declaration Regarding the Manufacture and Use of In-house Devices

Name of the Health Institution	Tallaght University Hospital
Address	Belgard Road, Tallaght, Dublin 24, D24NR0A

The devices described in this document are only manufactured and used in the health institution named above. They meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided where applicable general safety and performance requirements are not met.

Declaration Completed By:

Name:		Name:	
Role:	Laboratory Manager	Role:	Laboratory Director
Signature:		Signature:	
Date:	23.03.2026	Date:	23.03.2026

Type	Discipline	Device identification(e.g. name, description, UDI number)	Device Type(IVD/MD)	Risk Class of the Device	Manufacturer intended use as per CE mark (if applicable)	Intended use in Tallaght University Hospital	Information on, and justification for, application GSPR that are not fully met
Reagent	Blood Transfusion	Blood Transfusion: Grifols Weak D Control Cells (Tube method)	IVD	Class D	Verification of RHD typing	In house method - used for investigation of weak RHD reactions.	IFU recommends use of Grifols tube test antisera. Testing in-house is performed using a third party antisera (note: clones used are the same clones specified in IFU - anti-D MS201, Rum-1). In house method validation complete. IQC, EQA in place. All suspected weak D's are referred to the National Blood Centre for confirmation.
Reagent	Blood Transfusion	Blood Transfusion: NBS antibody panel (BioVue cassettes)	IVD	Class C	Antibody investigation/ Identification (tube method).	In house method - used as exclusion cells during antibody investigations	Used in BioVue technology (IFU states tube use only). In house method validation complete. IQC, EQA in place. Not used a primary panel, used for exclusion cells only.
Equipment	Blood Transfusion	Blood Transfusion;Electronic Issue of Red Cells using WinPath Software	IVD		Laboratory Information System (WinPath) not CE marked by supplier.	Electronic Issue of Red Cells using WinPath Software	Not marked as an IVD by the supplier (Clinisys). LIMS validated, Electronic issue assessed and accredited by INAB. Manual checks and interpretations performed by medical scientist throughout each process. Automated blood grouping analyser will hold uninterpretable results.
Reagent	Haematology	Haematology;Iron Stain	IVD	Class C	N/A	The purpose is to stain bone marrow cells for microscopical examination. Commercial control material unavailable; Positive control slides sourced from Histopathology (liver sections) Laboratory Consultants confirm correct staining pattern observed	Commercial control material unavailable.
Reagent	Haematology	Haematology; RPMI Heparin Solution (Sample Collection Media)	IVD	Class C	N/A	In House prepared media for preservation of sample material (Bone marrow aspirates and CSF specimens for immunophenotyping analysis)	
Equipment	Haematology	Haematology; BD FACS Canto II used for Haematological Immunophenotyping Acute Leukaemia Panel Chronic Lymphoproliferative Panel CSF Immunophenotyping PNH (Paroxysmal Nocturnal Haemoglobinuria) analysis by flow cytometry	IVD	Class C		The diagnosis and monitoring of haematological malignancies & disorders.	Justification for use: BD FACS Canto II is CE Marked, IVDR was introduced after purchase of equipment. For antibody panels- IVDR compliant antibodies are used where commercially available but some antibodies are marked RUO, there are currently no IVDR compliant versions commercially available, and the antibodies are critical for diagnosis and monitoring of haematological malignancies & disorders.
Equipment	Microbiology	Microbiology;Testing respiratory samples for MTB and MTB Rif resistance using GeneXpert and Xpert MTB/RIF Ultra	IVD/CE Marked	Class D	Used as manufacture intended. Occasionally used to test unvalidated specimens	To detect M.tuberculosis complex and Rifampicin resistance	Unvalidated specimens are not reported. IVDR status unknown. Company has been contacted.
Equipment	Microbiology	Microbiology; Investigation of specimens for Mycobacterium Species on the MGIT culture system	IVD/CE Marked	Class D	Used as manufacture intended. Samples other than sputa and BAL's are also tested but not validated	To investigate specimens for the presence of Mycobacterium species	No validated method for testing of specimen types other than sputa nad BAL's. IVDR status unknown. Company has been contacted.
Equipment	Microbiology	Microbiology; Testing CSF samples for the N. meningitis using Biofire Film Array and ME Panel	IVD/CE Marked	Class C	Used as manufacture intended. Non CE marked controls used	To detect N. meningitis, CMV and other pathogens	No other suitable controls available. IVDR status unknown. Company has been contacted.
Equipment	Microbiology	Microbiology;Testing Respiratory samples for SARS CoV/flu viruses using Biofire Film Array and RP2.1 plus	IVD/CE Marked	Class D	Used as manufacture intended. Non CE marked controls used	To detect SARS-CoV-2 RNA /Flu / RSV in clinical samples	No other suitable controls available. IVDR status unknown. Company has been contacted.