Name of Health Institution: Public Health Laboratory Dublin

Address: Cherry Orchard Hospital,
Ballyfermot
Dublin 10
D10 X997

The devices described in this document are only manufactured and used in the health institution named above.

The devices meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746)

Declaration completed by:

Name: Tee Keat Teoh

Role: Consultant Microbiologist

Signature: 

Date:13/12/2024

Name: Anne Carroll

Role: Chief Medical Scientist

Signature: 

Date: 13/12/2024

Device identification	Device type (IVD/MD)	Risk class of device	Intended purpose	Applicable GSPR Fully met	Information on & justification for applicable GSPR that are not fully met
Illumina DNA prep kit	IVD	B	For library preparation of bacterial DNA for whole genome sequencing (WGS)	Y	N/A
Automated library preparation for whole genome sequencing using TECAN Fluent® Liquid Handler. Script is derived from Illumina protocol	IVD	B	System used for automated library preparation for next step of whole genome sequencing	Y	N/A
Illumina NextSeq 1000 and MiSeq (Sequencers for WGS)	IVD	B	Sequencing of prepared libraries for WGS of bacterial isolates	Y	N/A
FastStart SYBR Green Master Mix for VTEC PCR.	IVD	C	Used for detection of stx1 and stx2 genes for diagnosis of VTEC from stool samples	Y	N/A
Primers for VTEC testing including *eae*, *stx1*, *stx2* and serogroups O157, O26, O104, O145, O103 and O111. Additional stx2f primer. Produced for PHL Dublin by Sigma-Aldrich	IVD	C	Used for diagnosis of VTEC and serogrouping of recovered isolates from stool samples.	Y	N/A
Whole genome sequencing analysis performed for C. difficile, VTEC and Campylobacter using commercial software Ridom SeqSphere	IVD (Software)	C	Analysis of data from Illumina Sequencers to allow extraction of data for clinical reporting, outbreak investigation and surveillance purposes	Y	N/A