

Clinical Directorate of Laboratory Medicine, Beaumont Hospital					
Doc No:	QF-GEN-0046	Revision	1	Active Date	29 <sup>th</sup> April 2025
Declaration Regarding the Manufacture and Use of In-House Devices					



**NAME OF THE HEALTH INSTITUTION:** Clinical Directorate of Laboratory Medicine, Beaumont Hospital

**ADDRESS:** Beaumont Hospital, Beaumont Road, Beaumont, Dublin 9, D09C562

The devices described in this declaration meet the general safety and performance requirements (GSPR) of in vitro diagnostic medical devices regulation (EU 2017/746). These devices are only manufactured and used in Beaumont Hospital.

**DECLARATION COMPLETED BY:**

**Name:** Patrick Thornton

**Role:** Clinical Director

**Date:** 29<sup>th</sup> April 2025

**Name:** John Crumlish

**Role:** Laboratory Manager

**Date:** 29<sup>th</sup> April 2025

**Name:** Paula Conran

**Role:** Quality Manager

**Date:** 29<sup>th</sup> April 2025

**Clinical Directorate of Laboratory Medicine, Beaumont Hospital**

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<b>Device Identification (e.g. Name, description)</b>	<b>Device Type (IVD/MD)</b>	<b>Risk Class of the Device</b>	<b>Intended Purpose</b>	<b>Applicable GSPR Fully Met? Y/N</b>	<b>Information on and justification for application GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)</b>
Detection of mutations by Next Generation Sequencing for Lung, Colorectal, Breast, Thyroid Cancer and Melanoma to guide treatment	IVD	C	Predictive biomarker for targeted treatment of cancer types	Y	N/A
Detection of BRCA1/2 mutations	IVD	C	Predictive biomarker for PARPi therapy	Y	N/A
Detection of BRCA1/2 Large genomic rearrangements	IVD	C	Predictive biomarker for PARPi therapy	Y	N/A
HRD testing	IVD	C	Predictive biomarker for PARPi therapy	Y	
Euroclonality testing-detect lymphoma alterations	IVD	C	Diagnosis, prognosis and treatment options for lymphoma	Y	N/A

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MLH1 methylation	IVD	C	Predictive biomarker for targeted treatment of cancer types	Y	N/A
Microsatellite instability testing	IVD	C	Predictive biomarker for targeted treatment of cancer types	Y	N/A
IDH 1/2 sequencing	IVD	C	Criteria for diagnosing specific brain tumours	Y	N/A
MGMT methylation	IVD	C	Indicates the patient response to treatment	Y	N/A
aCGH	IVD	C	Criteria for diagnosing specific brain tumours	Y	N/A
DNA methylation profiling	IVD	C	Diagnosis, prognosis and treatment option for brain tumours	Y	N/A
BRAF fusion	IVD	C	Diagnosis, prognosis and treatment option for brain tumours	Y	N/A
DNA extraction FFPE	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	N/A

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DNA extraction high molecular weight (Blood, bone marrow aspirate)	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	N/A
RNA extraction FFPE	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	N/A
Detection of RNA alterations to guide diagnosis, prognosis and treatment options for patients with Brain tumours	IVD	C	Diagnosis, prognosis and treatment option for brain tumours	Y	N/A
<b>Analysis Software</b>					
JSI SeqNext	Software	C	Analysis of Next generation Sequencing assay	Y	N/A
Genome Studio software	Software	C	Analysis of DNA methylation profiling	Y	N/A
DKFZ classifier	Software	C	Analysis of DNA methylation profiling	Y	N/A
Euroclonality application - Basespace	Software	C	Analysis of Euroclonality panel	Y	N/A
Agilent array GenePix software	Software	C	Analysis of aCGH data	Y	N/A

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Archer fusion plex analysis	Software	C	Analysis of Next generation Sequencing assay	Y	N/A
Pyromark software	Software	C	Analysis of methylation and IDH sequencing	Y	N/A
SeqStudio	Software	C	Analysis of MSI and BRCA1 and BRCA2 MLPA	Y	N/A
Illumina Dragen Analysis software	Software	C	HRD analysis	Y	N/A