Blueprint Genetics

Public declaration regarding the manufacture and use of in-house devices by health institutions

Name of health institution: Blueprint Genetics Oy
Address: Keilaranta 16 A-B, 02150 Espoo, Finland

Blueprint Genetics Oy declares that the devices described in the accompanying table are only manufactured and used at Blueprint Genetics Laboratory in Espoo and do meet the Article 5.5 including applicable general safety and performance requirements (GSPR) of the in vitro diagnostic (IVD) medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Table of in-house devices:

Device identification (name, reference number)	Risk class of the IVD device	Intended purpose	Applicable GSPR fully met? (Y/N)	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)
ddPCR Platform (DPC-3000)	Class C	The Blueprint Genetics ddPCR Platform is a quantitative and semi-automated droplet digital PCR system intended for confirmation of copy number variations (CNVs) initially identified by next-generation sequencing (NGS) -based devices used to aid to diagnosis of suspected inherited, monogenic, and highly penetrant genetic disorders. The type of specimen required is genomic DNA derived from whole blood and saliva, obtained from individuals undergoing genetic testing.	Y	Not Applicable

		This device is used exclusively within Blueprint Genetics for in-house in vitro diagnostic use in accordance with Regulation (EU) 2017/746.		
Sanger Platform (SAN-4000)	Class C	The Blueprint Genetics Sanger Platform is a qualitative, semi-automated Sanger sequencing system intended for confirmation of single nucleotide variants and short deletions and insertions initially identified by next-generation sequencing devices used to aid to diagnosis of suspected inherited, monogenic, and highly penetrant genetic disorders. The type of specimen required is genomic DNA derived from whole blood and saliva, obtained from individuals undergoing genetic testing. This device is used exclusively within Blueprint Genetics for in-house in vitro diagnostic use in accordance with Regulation (EU) 2017/746.	Y	Not Applicable

In Espoo on July 6, 2026

Olli Mikkonen
Director of Quality and Regulatory Affairs
Blueprint Genetics