

Device Schedule: Class D, C and B devices

Class C devices

W0106 – Genetic Testing

IVP 3011 – In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)

Intended purpose

In vitro diagnostic nucleic acid assays based on Multiplex Ligation-Dependant Amplification (MLPA) or melt PCR technology intended for the detection of inborn or acquired gene or chromosome alterations.
