

Declaration of Conformity DoC in-house devices

Public declaration regarding the manufacture and use of in-house devices by Life Genomics.

Name of health institution: Life Genomics AB
Address: Odinsgatan 28
411 03 Göteborg
Sweden

Life Genomics AB declares that the devices described in the accompanying table are only manufactured and used in Life Genomics AB and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745) or of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location: Göteborg 2026-05-26



Sebastjan Gergeta, President of the board (Styrelseordförande) Life Genomics AB

Table of in-house devices:

Device identification (e.g. name, description, reference number)	Device type (IVD/MD)	Risk class of the device ²	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)
Capitainer TSH B50 Basic UDI-DI: 735009019TSH-CapitainerF8	IVD	Class B	Determination of TSH from Capitainer B50 serves as the initial test in hypothyroidism diagnostics and for monitoring treatment effects in diagnosed individuals.	Yes	-

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Capitainer PSA B10 Basic UDI-DI: 735009019PSA- CapitainerZN	IVD	Class B	Determination of PSA from Capitainer B as part of organized screening for prostate cancer.	Yes	
GenePlanet NIPT Basic UDI-DI: 735009019GenePlanetNIPT 6A	IVD	Class B	Prenatal screening test on cell-free DNA (cfDNA) extracted from maternal plasma used for providing risk information on selected fetal chromosomal abnormalities and fetal sex determination.	Yes	

² The risk class of the device has been determined by using Annex VIII of the IVDR guidance MDCG 2020-16.