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 2025-12-22

Göran Jacobsson, CEO (VD) 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	-
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	

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

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