

Name of health institution:

Glycanostics® s.r.o.

Address:

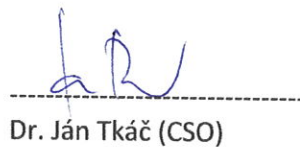
Kudláková 1848/7, 841 01 Bratislava - mestská časť Dúbravka, Slovakia

Glycanostics® s.r.o. declares that the devices described in the accompanying table are only manufactured and used in Glycanostics® s.r.o. and meet the applicable general safety and performance requirements (GSPR) of the *in vitro* diagnostic medical devices Regulation (EU 2017/746).

Date and location:



Eva Kováčová, FCCA (CEO)



Dr. Ján Tkáč (CSO)



Dr. Tomáš Bertók CTO

Table of in-house devices:

Device identification	Device type	Risk class of the device	Intended purpose	Applicable GSPR fully met?	Information on and justification for applicable GSPR that are not fully met
Giasay Prostate Cancer	IVD	Class C	The Giasay prostate Cancer is intended for use in <i>in vitro</i> diagnostic laboratories by trained healthcare professionals to quantitatively determine the presence of cancer-specific fPSA glycoform in the serum samples of men 45 years or older. The test should be used as a second opinion test to increase the accuracy of correctly prescribing prostate biopsy for cancer detection.	Yes	N/A