

Name of health institution:

**MultiplexDX, s.r.o.**

Address:

**Ilkovičova 8, 841 04 Bratislava, Slovakia**

MultiplexDX s.r.o. declares that the devices described in the accompanying table are only manufactured and used in MultiplexDX 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: 26.05.2023, Bratislava

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Pavol Čekan, PhD (CEO)

Table of in-house devices:

<b>Device identification</b>	Multiplex8+
<b>Device type</b>	IVD
<b>Risk class of the device</b>	Class C
<b>Intended purpose</b>	The Multiplex8+ breast cancer test assesses RNA- based biomarkers by conducting a visualization (RNA-FISH) and a sequencing test to survey gene expression in a spatially resolved manner. The test must be performed by trained personnel at MultiplexDX's specialized laboratory. The test is used as 2 <sup>nd</sup> opinion for oncologist to predict potential of therapies in breast cancer.
<b>Applicable GSPR fully met?</b>	Yes
<b>Information on and justification for applicable GSPR that are not fully met</b>	N/A