

EU DECLARATION OF CONFORMITY

No 2/2025v01

Manufacturer:	DiagnostIQ Ltd.	
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The EU Declaration of Conformity is issued under the sole responsibility of DiagnostIQ Ltd.

Product name:	Ai Life SMART MEDICAL REPORT
Trade name:	Ai Life SMART MEDICAL REPORT
Basic-UDI	599957791SMRBASIC1S7 599957791SMRNORMAL12Z 599957791SMRPREM1DG 599957791SMRTHYRB16M 599957791SMRTHEXT001XN 599957791SMRTHPRE001WS
Intended use:	Ai Life SMART MEDICAL REPORT is based on large health data sets and can estimate the risk of 14 disease groups, providing general information on laboratory test results and their possible variations. SMART MEDICAL REPORT includes your personal data, key details of the laboratory test, report identifier, UDI-DI and UDI-PI identifiers. The latter includes the version number of the software used, ensuring maximum data protection and traceability. The information is released after sample validation by a specialist.

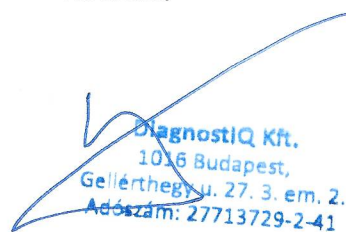
The device is classified as a Class A IVD device in accordance with Rule 5 of Annex VIII of Regulation (EU) 2017/746 of the European Parliament and of the Council.

We hereby declare and certify that the device listed in this Declaration of Conformity complies with the following regulations and standards:

- The provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council.
- Section 2.5 and Part II of the Harmonised Plan of the European Commission (COM 2018) 795.
- The standards ISO/IEC/IEEE 12207:2017 and ISO/IEC 62304:2006/Amd_1:2015.
- The software development activities are carried out in accordance with the requirements of ISO 9001:2015 and ISO 13485:2016.

Place and date of issue:

Budapest, April 14, 2025.



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Name and position of the signatory:

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