EU DECLARATION OF CONFORMITY

MANUFACTURER: Saventic Health Sp. z o.o.
Władysława Łokietka 5
87-100 Toruń, Poland

declares, at its own responsibility, the following medical device:

SARAH Platform

computer software supporting screening tests and the process of early diagnostics of rare diseases by means of analysis of results of laboratory testing and descriptive medical documentation with the use of artificial intelligence, available in the following options:

software version: 1.0.2020 and subsequent versions

pursuant to the regulation of the Minister of Health of 5 November 2010 on the manner of classification of the medical devices, was classified as **class 1 medical device, in accordance with rule 12.**

The device complies with the applicable requirements of the Act of 20 May 2010 on medical devices and **Council Directive 93/42/EEC.**

The conformity assessment procedure was in compliance with Annex VII to the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices.

In order to prove safety and effectiveness of operation of the medical device, the following standards have been applied for conformity assessment:

EN 1041:2008
Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2016
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, including corrected version 2016-12-15))

EN ISO 14971:2012
Medical devices - Application of risk management to medical devices.

EN 62366:2008
Medical devices - Application of usability engineering to medical devices.

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EN 62304:2006/AC:2008
Medical device software - Software life cycle processes

EN 82304-1:2017-10
Health software - Part 1: General requirements for product safety

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Full name of the approving person:

Szymon Piątkowski Szymon Piątkowski

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