EU DECLARATION OF CONFORMITY

DYNEX TECHNOLOGIES, spol. s r.o.
Vodičkova 791/41, 110 00 Praha 1
Czech Republic

We declare under our sole responsibility that the product:

Product Name	DYNABLOT PLUS DYNABLOT PLUS 7
Catalogue No.	D7144-P6 D7144-P7
UDI-DI	859421131029-71K6
Risk Class	Class A, rule 5b

meets the demands of the following European documents:

Regulation 746/2017 **on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU**

Directive 2014/30/EU **Electromagnetic compatibility Directive**

In addition, the following standards were used and followed for the conformity assessment:

EN 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements

EN 14971 Medical devices – Application of risk management to medical devices

EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

EN 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

Praha, 20.5. 2022
Place and date of issue

Ing. Zora Hanzlíková
CEO
Signed on behalf of DYNEX TECHNOLOGIES, spol. s r.o.