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	DYNAMIC
Catalogue No.	D0107
UDI-DI	859421131033-01HJ
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.