

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 COMFORT
Catalogue No.	D1107
UDI-DI	859421131040-11HB
Risk Class	Class A, rule 5b

meets the demands of the following European documents:

Regulation 746/2017	on <i>in vitro</i> diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
Directive 2014/30/EU	Electromagnetic compatibility Directive
Directive 2014/35/EU	for electrical equipment designed for use within certain voltage limits
Directive 2015/863/EU	on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The following technical standards have been applied for the Conformity Assessment:

EMC:	EN 55011 EN 61326-1
LVD:	EN 61010-1 EN 61010-2-101
Others:	EN ISO 14971 EN ISO 13485

Praha, 11.01.2023
Place and date of issue:



Ing. Zora Hanzlíková
CEO

Signed on behalf of DYNEX TECHNOLOGIES, spol. s r.o.