

## **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 HEAT
	DYNABLOT HEAT VL
	DYNABLOT HEAT FR
	DYNABLOT HEAT NLM
Catalogue No.	D0905
	D0905-01
	D0905-02
	D0905-03
UDI-DI	859421131001-09GK
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

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, 20.5.2022 Place and date of issue: Ing. Zora Hanzlíková

CEO