

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

DYNABLOT Heat VL (product name), D0905-01 (order number)

meets the demands of Directives

Directive 98/79/EC **In vitro diagnostic medical devices**

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

Directive 2014/35/EU **for electrical equipment designed for use within certain voltage limits**

The following technical regulations have been applied for the conformity assessment:

EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
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 diagnostics (IVD) medical equipment
EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices

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