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 Plus 6P (product name)

D7144-P6 (order number)

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meets the demands of Directives

Directive 98/79/EC	**In vitro diagnostic medical devices, Annex III of 27 October 1998**
Directive 2014/35/EU	**for electrical equipment designed for use within certain voltage limits**
Directive 2014/30/EU	**Electromagnetic compatibility Directive**

The following standards are applied:

EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements
EN 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2011	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
EN 61010-2-101:2003	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 13485:2016	Medical devices

Praha, 24.11.2010
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Ing. Zora Hanzlíková
Director