

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 (product name)

D7144-P7 (order number)

meets the demands of Directives

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

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

Directive 2011/65/EU **on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

The following standards are applied:

EN 61326:2013 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, 11. 7. 2012
Date of revision: 24.04.2019
Place and date of issue



Ing. Zora Hanzlíková

director