

## 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

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**DYNAMIC** (product name)

**D0107** (order number)

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meets the demands of Directives:

**Directive 98/79/EC** for **in vitro diagnostic medical devices**

**Directive 2014/30/EU** for **electromagnetic compatibility**

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

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The following standards has been applied:

ČSN EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

ČSN EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

ČSN EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

ČSN EN ISO 14971 Medical devices - Application of risk management to medical devices

Place of issue: Buštěhrad

Date of issue: 15.10.2018



Ing. Zora Hanzlíková  
CEO