

# 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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**DYNAREAD** (product name), D5206 (order number)

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meets the demands of Directives

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

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

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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

Prague, 1.8. 2016  
Place and date of issue

A handwritten signature in blue ink, appearing to read "Hanzlíková".

Ing. Zora Hanzlíková  
director