

CE 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

Product name: **DYNAREAD**

Order numbers: **D5206-E**

meets the demands of directives:

98/79/EC in vitro diagnostic medical devices

2014/30/EU electromagnetic compatibility

The following technical regulations have been applied for the Conformity Assessment:

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

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

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

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

Place of issue: Prague

Date of issue: 11.02.2020



Ing. Zora Hanzlíková
CEO