

Certificate of Approval

This is to certify that the Management System of:

DYNEX TECHNOLOGIES, spol. s r.o.

Vodičkova 791/41, 110 00 Praha 1 - Nové Město, Czech Republic

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 – 0053492, ISO 9001 – 0053493

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and production of in vitro diagnostic medical devices and associated equipment.



Paul Graaf

Area Operations Manager North Europe

Issued by: Lloyd's Register EMEA

for and on behalf of: Lloyd's Register Quality Assurance Limited



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Certificate Schedule

| Location | Activities |
|---|---|
| DYNEX TECHNOLOGIES, spol. s r.o. Vodičkova 791/41, 110 00 Praha 1 - Nové Město, Czech Republic | ISO 13485:2016 Design, development and production of in vitro diagnostic medical devices and associated equipment. ISO 9001:2015 Design, development and production of in vitro diagnostic medical devices and associated equipment. |
| DYNEX LABORATORIES, s.r.o. Vodičkova 791/41, 110 00 Praha 1 - Nové Město, Czech Republic | ISO 13485:2016 Design, development and production of in vitro diagnostic medical devices and associated equipment. ISO 9001:2015 Design, development and production of in vitro diagnostic medical devices and associated equipment. |
| DYNEX LabSolutions, s.r.o. Lidická 977, 273 43 Buštěhrad, Czech Republic | ISO 13485:2016 Trade and distribution of medical devices. |



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