

Certificate of Approval

This is to certify that the Management System of:

DYNEX LABORATORIES, s.r.o.

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

has been approved by LRQA to the following standards:

ISO 13485:2016 | ISO 9001:2015



P.G. Cornelissen - Area Manager North Europe

Issued by: Lloyd's Register EMEA

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

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.

Current issue date: 7 March 2019
Expiry date: 10 April 2020
Certificate identity number: 10177904

Original approval(s):
ISO 13485 – 11 April 2005
ISO 9001 – 11 April 2005

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

The scope of this approval is applicable to:

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



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Certificate Schedule

Certificate identity number: 10177904

Location	Activities
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.
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.



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