

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



Paul Graaf - Area Operations Manager North Europe

Issued by: Lloyd's Register Nederland B.V.

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: 11 April 2020
Expiry date: 10 April 2023
Certificate identity number: 10260541

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

Approval number(s): ISO 13485 – 0053492

The scope of this approval is applicable to:
Design, development and production of in vitro diagnostic medical devices and associated equipment.



001

Certificate Schedule

Certificate identity number: 10260541

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.
DYNEX LabSolutions, s.r.o. Lidická 977, 273 43 Buštěhrad, Czech Republic	ISO 13485:2016 Trade and distribution of medical devices.
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.



001