

Current issue date: Certificate identity number: 11 April 2023 10 April 2026 10514373

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

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract. Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

# **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 LRQA 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, Production, Trade, Distribution and Service of in vitro diagnostic medical devices.

#### **Paul Graaf**

Area Operations Manager, Europe

Issued by: LRQA Limited



LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.

Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



### **Certificate Schedule**

#### Location DYNEX TECHNOLOGIES, spol. s r.o.

### **Activities**

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

#### ISO 13485:2016, ISO 9001:2015

Design, Development, Production, Trade, Distribution and Service of in vitro diagnostic medical devices.

#### DYNEX LabSolutions, s.r.o.

Lidická 977, 273 43 Buštěhrad, Czech Republic

#### ISO 13485:2016

Design, Development, Production, Trade and Distribution of in vitro diagnostic medical devices.

#### DYNEX LABORATORIES, s.r.o.

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

#### ISO 13485:2016, ISO 9001:2015

Design, Development, Production, Trade and Distribution of in vitro diagnostic medical devices.