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Original approval(s): ISO 13485 - 13 July 2021

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Certificate of Approval

This is to certify that the Management System of:

Ecoli Dx, s.r.o.

Purkyňova 74/2, 110 00 Praha 1 - Nové Město, Czech Republic

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 0079454

The scope of this approval is applicable to:

Design, development, production, distribution and servicing of in vitro diagnostic medical devices of risk class A, B, C.

Paul Graaf

Area Operations Manager, Europe

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