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FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland
Coverage of Certificate:	Design, manufacture and final inspection
Product category:	Reagents and reagent products for detection and quantification of toxoplasmosis, for diagnosing phenylketonuria, and for determining chlamydia
Valid until:	26 May 2025

The manufacturer´s quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Digitally signed by Ciaiu Victoria
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Location: Moldova
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Valid from: 25 May 2022

Aliisa Siljander

Riikka Kylväjä

Certificate no.

C-02-1172-794-22

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

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Attachment 1 to the Certificate number: C-02-1172-794-22

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for detection and quantification of toxoplasmosis. GMDN-code(s): 52441, 52440, 52436, 60897
Products:	The certificate covers the following products:

Name	*Model*
Neonatal Toxoplasma gondii IgM FEIA	6199802
Neonatal Toxoplasma gondii IgM EIA	6199804
Toxoplasma gondii IgG EIA	6600100
Toxoplasma gondii IgG Avidity EIA	6600140

Date:	Valid from: 25 May 2022

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Riikka Kylväjä

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Attachment 2 to the Certificate number: C-02-1172-794-22

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for diagnosing phenylketonuria. GMDN-codes: 58960,53512, 53513, 58190, 58191, 58192, 58193
Products:	The certificate covers the following products:

Name	*Model*
Neonatal Phenylalanine	6199895
	6199896
	6199897
Neonatal Phenylalanine calibrators	6190940
Neonatal Phenylalanine controls	6190930
NeoMass AAAC	7100100
NeoMass AAAC 3.0	7100120
NeoMass AAAC Plus	7100110
NeoMass AAAC DBS Controls	710010003
NeoMass AAAC Internal Standard, Labeled Amino Acids	710010004
NeoMass AAAC Extraction Solution	710010008
NeoMass AAAC Eluent Solution	710010009
NeoMass AAAC Plus DBS Controls	710011003
NeoMass AAAC Plus Internal Standard, Labeled Amino Acids	710011004
NeoMass AAAC Plus Extraction Solution B	710011009
NeoMass AAAC Plus Eluent Solution	710011010

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Attachment 3 to the Certificate number: C-02-1172-794-22

Manufacturer:	Labsystems Diagnostics Oy Tiilitie 3 FI-01720 Vantaa Finland
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for determining chlamydia. GMDN-codes: 50733, 50737, 50741, 50721, 50719, 50768, 50773, 50727, 58957
Products:	The certificate covers the following products:

Name	*Model*
Chlamydia pneumoniae IgM EIA	6111320
Chlamydia pneumoniae IgG EIA	6111300
Chlamydia pneumoniae IgA EIA	6111310
Chlamydia pneumoniae IgG/IgM Micro-IF test	6108380
	6108382
Chlamydia pneumoniae IgA Micro-IF test	6108390
	6108392
Chlamydia pneumoniae Micro-IF slides	6108384
Chlamydia trachomatis IgG EIA	6111101
Chlamydia trachomatis IgA EIA	6111111
Biocard™ C. pneumonia IgM	3-034-000
M. pneumoniae + C. pneumoniae Duplex Real-Time PCR	8100100
	8101100
	8100101

Date:	Valid from: 25 May 2022

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