

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Labsystems Diagnostics Oy
Tiilitie 3
FI-01720 Vantaa
Finland

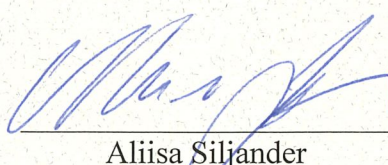
Coverage of Certificate: Design, manufacture and final inspection

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).

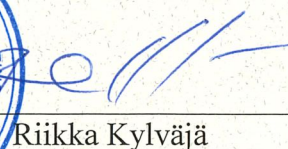
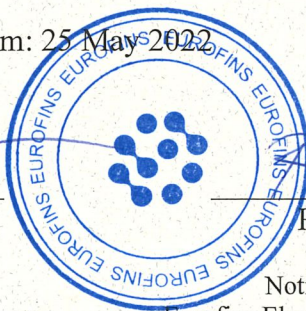
Valid from: 25 May 2022



Aliisa Siljander

Certificate no.

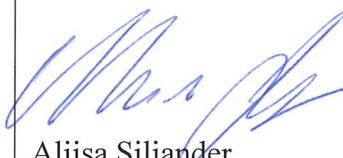
C-02-1172-794-22



Riikka Kylväjä

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

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: <table> <thead> <tr> <th><i>Name</i></th><th><i>Model</i></th></tr> </thead> <tbody> <tr> <td>Neonatal Toxoplasma gondii IgM FEIA</td><td>6199802</td></tr> <tr> <td>Neonatal Toxoplasma gondii IgM EIA</td><td>6199804</td></tr> <tr> <td>Toxoplasma gondii IgG EIA</td><td>6600100</td></tr> <tr> <td>Toxoplasma gondii IgG Avidity EIA</td><td>6600140</td></tr> </tbody> </table>	<i>Name</i>	<i>Model</i>	Neonatal Toxoplasma gondii IgM FEIA	6199802	Neonatal Toxoplasma gondii IgM EIA	6199804	Toxoplasma gondii IgG EIA	6600100	Toxoplasma gondii IgG Avidity EIA	6600140
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Date:	Valid from: 25 May 2022										
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EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI21741879

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: <table> <thead> <tr> <th><i>Name</i></th><th><i>Model</i></th></tr> </thead> <tbody> <tr> <td>Neonatal Phenylalanine</td><td>6199895</td></tr> <tr> <td></td><td>6199896</td></tr> <tr> <td></td><td>6199897</td></tr> <tr> <td>Neonatal Phenylalanine calibrators</td><td>6190940</td></tr> <tr> <td>Neonatal Phenylalanine controls</td><td>6190930</td></tr> <tr> <td>NeoMass AAAC</td><td>7100100</td></tr> <tr> <td>NeoMass AAAC 3.0</td><td>7100120</td></tr> <tr> <td>NeoMass AAAC Plus</td><td>7100110</td></tr> <tr> <td>NeoMass AAAC DBS Controls</td><td>710010003</td></tr> <tr> <td>NeoMass AAAC Internal Standard, Labeled Amino Acids</td><td>710010004</td></tr> <tr> <td>NeoMass AAAC Extraction Solution</td><td>710010008</td></tr> <tr> <td>NeoMass AAAC Eluent Solution</td><td>710010009</td></tr> <tr> <td>NeoMass AAAC Plus DBS Controls</td><td>710011003</td></tr> <tr> <td>NeoMass AAAC Plus Internal Standard, Labeled Amino Acids</td><td>710011004</td></tr> <tr> <td>NeoMass AAAC Plus Extraction Solution B</td><td>710011009</td></tr> <tr> <td>NeoMass AAAC Plus Eluent Solution</td><td>710011010</td></tr> </tbody> </table>	<i>Name</i>	<i>Model</i>	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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Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI21741879

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: <table> <thead> <tr> <th><i>Name</i></th><th><i>Model</i></th></tr> </thead> <tbody> <tr> <td>Chlamydia pneumoniae IgM EIA</td><td>6111320</td></tr> <tr> <td>Chlamydia pneumoniae IgG EIA</td><td>6111300</td></tr> <tr> <td>Chlamydia pneumoniae IgA EIA</td><td>6111310</td></tr> <tr> <td>Chlamydia pneumoniae IgG/IgM Micro-IF test</td><td>6108380</td></tr> <tr> <td></td><td>6108382</td></tr> <tr> <td>Chlamydia pneumoniae IgA Micro-IF test</td><td>6108390</td></tr> <tr> <td></td><td>6108392</td></tr> <tr> <td>Chlamydia pneumoniae Micro-IF slides</td><td>6108384</td></tr> <tr> <td>Chlamydia trachomatis IgG EIA</td><td>6111101</td></tr> <tr> <td>Chlamydia trachomatis IgA EIA</td><td>6111111</td></tr> <tr> <td>Biocard™ C. pneumonia IgM</td><td>3-034-000</td></tr> <tr> <td>M. pneumoniae + C. pneumoniae Duplex Real-Time PCR</td><td>8100100</td></tr> <tr> <td></td><td>8101100</td></tr> <tr> <td></td><td>8100101</td></tr> </tbody> </table>	<i>Name</i>	<i>Model</i>	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
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