

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: 24<sup>th</sup> April 2019

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).

Tampere, 24<sup>th</sup> April 2014

  
Aliisa Siljander

Certificate no.



VTT-C-11133-02-1172-515-14



  
Markku Helminen

Notified Body no. 0537:  
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**Attachment 2 to the Certificate number: VTT-C-11133-02-1172-515-14**

<b>Manufacturer:</b>	Labsystems Diagnostics Oy Tiilitie 3, FI-01720 Vantaa Finland																	
<b>Activity and product category:</b>	Design, manufacture and final inspection; reagents and reagent products for diagnosing phenylketonuria																	
<b>Products:</b>	<p>The certificate covers the following products:</p> <table><thead><tr><th><i>Name</i></th><th><i>GMDN code</i></th><th><i>Product code</i></th></tr></thead><tbody><tr><td>- Neonatal Phenylalanine</td><td>58960</td><td>6199895 6199896 6199897</td></tr><tr><td>- Neonatal Phenylalanine calibrators</td><td>53512</td><td>6190940</td></tr><tr><td>- Neonatal Phenylalanine controls</td><td>53513</td><td>6190930</td></tr><tr><td>- NeoMass AAAC</td><td>58190</td><td>7100100</td></tr></tbody></table>			<i>Name</i>	<i>GMDN code</i>	<i>Product code</i>	- Neonatal Phenylalanine	58960	6199895 6199896 6199897	- Neonatal Phenylalanine calibrators	53512	6190940	- Neonatal Phenylalanine controls	53513	6190930	- NeoMass AAAC	58190	7100100
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<b>Date:</b>	Tampere, 11 <sup>th</sup> November 2015																	
	<div><div> Tuomas Toivonen</div><div> Mikko Soikkeli</div></div>																	



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