



Declaration of Conformity

Identification of the legal entity	<p><b>Labsystems Diagnostics Oy</b>  <b>Tiilitie 3, 01720 Vantaa</b>  <b>Finland</b>  <b>Tel. +358-(0)20 155 7530</b>  <b>Fax. +358-(0)20 155 7521</b></p>
Identification of the device(s) concerned	<p><b>Neonatal Phenylalanine</b>  <b>(Prod.no. 6199895, 6199896 and 6199897)</b>  <b>Neonatal Phenylalanine Controls (Prod.no. 6190930)</b>  <b>Neonatal Phenylalanine Calibrators (Prod.no. 6190940)</b></p>

**We hereby declare that the above mentioned device complies with the requirements of Council Directive 98/79/EC and the corresponding Finnish National Act 629/2010 and to the following standards.**

Standards	<p><b>EN ISO 14971:2012</b>          Medical devices. Application of risk management to medical devices</p> <p><b>EN ISO 15223-1:2016</b>          Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 – General requirements</p> <p><b>EN ISO 13485:2016</b>          Medical devices – Quality management systems - Requirements for regulatory purposes</p> <p><b>EN 13612:2002</b>          Performance evaluation of <i>in vitro</i> diagnostic medical devices</p> <p><b>EN ISO 23640:2015</b>  <i>In vitro</i> diagnostic medical devices. Evaluation of stability of <i>in vitro</i> diagnostic reagents</p> <p><b>EN 13641:2002</b>          Elimination or reduction of risk of infection related to <i>in vitro</i> diagnostic reagents</p> <p><b>EN 13975:2003</b>          Sampling procedures used for acceptance testing of <i>in vitro</i> diagnostic medical devices – Statistical aspects</p>
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**EN ISO 18113-1:2011**

*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements

**EN ISO 18113-2:2011**

*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use

IVDD classification **Annex II list B**

Conformity assessment procedure **Annex IV of the Directive 98/79/EC**

Notified body **No. 0537 VTT Expert Services Ltd.**

Signature of the authorized person In Vantaa on the 4<sup>th</sup> of June, 2018

  
**LABSYSTEMS  
DIAGNOSTICS**  
Sameer D. Saraf  
Chief Operating Officer  
