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Declaration of Conformity

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

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

EN ISO 14971:2012
Medical devices. Application of risk management to medical devices

EN ISO 15223-1:2016
Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 – General requirements

EN ISO 13485:2016
Medical devices – Quality management systems - Requirements for regulatory purposes

EN 13612:2002
Performance evaluation of *in vitro* diagnostic medical devices

EN ISO 23640:2015
In vitro diagnostic medical devices. Evaluation of stability of *in vitro* diagnostic reagents

EN 13641:2002
Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents

EN 13975:2003
Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices – Statistical aspects

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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 4th of June, 2018

Sameer D. Saral
Chief Operating Officer

Labsystems Diagnostics Oy

Domicile Vantaa

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