Magellan

DIAGNOSTICS

CE DECLARATION OF CONFORMITY

LeadCare® Plus™ BloodLead System

Manufacturer: *Hersteller, Fabricante* *Fabricant, Produttore*	*Fabricante, Producent* *Tillverkare, Κατασκευαστής*	**Magellan Diagnostics** 101 Billerica Ave, Building 4 North Billerica, Massachusetts 01862 U.S.A
EU Authorized Representative: *EU-Bevollmächtigte* *Representante Autorizado por la UE* *Mandataire* *Rappresentante Autorizzato in Eu*	Representante Autorizado na UE EU-autoriseret repræsentant *EU Auktoriserad representant* *Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ*	**Ichor Technologies Ltd** 1 Paper Mews, 330 High Street Dorking, Surrey, RH4 2TU, UK

Magellan Diagnostics hereby declares that the products listed below conform to the European Union directive and standards identified in this declaration.

Magellan Diagnostics erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Magellan Diagnostics declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Magellan Diagnostics déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Magellan Diagnostics dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Magellan Diagnostics declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Magellan Diagnostics erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Magellan Diagnostics bekräftar härmed att produkt(er) listade nedan, vara förenlig(a) med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Magellan Diagnostics με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ενωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:

EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) – Annex I and III, *Excluding Section 6 for Self Test*

RoHS Directive 2002/95/EC

ISO 9001:2008, Quality Management System
ISO 13485:2003, Medical Devices – Quality Systems
21CFR Part 809.10, 812.5, 820.130-820.160(a), 820.30, 820.70
ISO 14971:2007, Medical Devices - Application of risk management to medical devices
EN 61010-1:2001 (2nd Edition),(IEC 1010-1) : Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101 Part 2: Particular Requirements for in-vitro diagnostic (IVD) medical equipment.
EN 61326:2002, Group 1, Class B , Electrical equipment for measurement, control and laboratory use – EMC requirements, Amendment 1:1998 – Immunity ; Industrial
ISO 15223:2007, Medical Devices – Symbols to be used with medical devices, labelling and information to be supplied
EN 980:2008, Graphical symbols for use in the labeling of medical devices
EN 375:2001, Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
EN 18113-3:2011, Instructions for use for in vitro diagnostic instruments for professional use
EN ISO 23640:2011 In vitro diagnostic medical devices; Evaluation of stability of in vitro diagnostic reagents

Reba Daoust
Director of QA/RA

8/22/2016
Date

Product(s) Produkt(e) Produto(s) Producto(s) Produkt(er) Produit(s Produkt(er) Prodotto(i) Προϊόντα	**Beginning** zu beginnen Inicio von Gældende fra A partir de From Première id. Εναρξη A partire da

Product	P/N	GMDN CODE	EDMA CODE	
LeadCare® Plus™ Analyzer System	82-0001	31646	21 01 10 01	July 2015
LeadCare® Plus™ Analyzer System	82-0002-R	31646	21 01 10 01	
LeadCare® Plus™ Blood Lead Test Kit	82-0004	31646	21 01 10 01	