Certificate of CE-Registration

mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

Phoenix Healthcare Solutions, LLC
2890 W State Road 84, Suite 105
Fort Lauderdale, FL 33312
USA

as stipulated and demanded by the aforementioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.
Lancing Devices	16-380	DE/CA09/0760/1265

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

August 2014

Werner Sander
President & CEO

Phoenix
Healthcare Solutions, LLC
"An Innovative Medical Manufacturer"

Declaration of Conformity Certificate

We M/s. Phoenix Healthcare Solutions Address: LLC, 2890 W State Road 84 | Suite 105, Fort Lauderdale, FL 33312| USA, declare with sole responsibility that our product, listed below meet the essential requirements of Council Directive 93/42/EEC as amended by 2007/47/EC OR Council Directive 98/79/EEC pertaining to Medical Device.

Sr. No.	Product Name	Trade Name	Product Description	UMDNS Code	Class	Rule
1	Lancing Devices	Adjustable Lancing Device ALT SITE Lancing Device AquaLance Lancing Device Assure-Let Lancing Device	The Lancing Device is small, fountain pen size applicators used together with single use blood lancets to obtain capillary blood samples needed for blood glucose monitoring or for other tests requiring one or two drops of blood	16380	Class-I	1

We hereby appoint M/s mdi Europa GmbH, Langenhagener Str.71, 30855 Hannover, Langenhagen,
Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Mr. Abe Wong
Manufacturing Representative

Date: 1st Aug 2014

8. August 2014

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mdi Europa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

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