

# EU Declaration of Conformity



## European Communities Council Directive 93/42/EEC as amended by 2007/47/EC Concerning Medical Devices

MD Diagnostics Ltd hereby declares that the products named have been designed, tested and found to comply with the relevant sections of the reference standards. The products comply with all essential requirements of the Directives. The product carries the CE Mark:

<b>General Product Name:</b>	CO Screen
<b>Date Placed on the Market:</b>	November 2015
<b>Manufacturer:</b>	MD Diagnostics Ltd 15 Hollingworth Court Turkey Mill Ashford Road Maidstone Kent ME14 5PP United Kingdom
<b>Intended Use:</b>	Measurement of Carbon Monoxide levels in exhaled breath
<b>Sterile:</b>	No
<b>Measuring Function:</b>	Yes: parts per million (ppm); %COHb;
<b>Harmonised Standards referenced or applied:</b>	BS EN 60601-1:2006 BS EN 60601-1-2:2007 BS EN 62304:2006 BS EN ISO 14971:2012 BS EN 1041:2008 BS EN 980:2008
<b>Conformity Assessment Procedure:</b>	Council Directive 93/42/EEC; as amended by 2007/47/EC Annex V
<b>Notified Body:</b>	SGS United Kingdom Ltd (0120)
<b>Directive Classification:</b>	Class IIa under rule 10

**Signed:**

A handwritten signature in black ink, appearing to read 'Martin Marsh', with a circular flourish at the end.

Martin Marsh  
Director

04<sup>th</sup> November 2015