

# CE Registration Certificate

This is to certify that, in accordance with the In Vitro Diagnostic Medical Device Directive 98/79/EC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

**OPTI Medical Systems  
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Roswell, GA 30076  
U.S.A**

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the following In Vitro Diagnostic Medical Device Registrations:

**See attached product listing**

**Emergo Europe Registration Number: NL/CA01/601529**

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the In Vitro Diagnostic Medical Devices fulfill the applicable requirements of Directive 98/79/EC.

January 2008



Rene van de Zande  
President & CEO  
Emergo Europe

**Countries of Registration:**

Austria	Italy
Belgium	Lithuania
Denmark	Luxembourg
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	The Netherlands

**Product Name:****OPTI Medical OPTI CCA Analyzer and OPTI Medical OPTI-CCA Analyzer with Touch Screen****Description:**

The OPTI Medical OPTI-CCA Analyzer is intended to be used for the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, Glucose, BUN (urea), tHb and SO<sub>2</sub> in samples of whole blood and pH, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, Glucose, and BUN (urea) in serum and plasma.

**Product Name:****OPTI Medical OPTI-R Analyzer****Description:**

The OPTI Medical OPTI-R Analyzer is intended to be used for the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, tHb and SO<sub>2</sub> in samples of whole blood and pH, Na<sup>+</sup>, K<sup>+</sup>, and Ca<sup>++</sup> in serum and plasma.

**Product Name:****OPTI Medical OPTI-LION Analyzer****Description:**

The OPTI Medical OPTI-LION Analyzer is intended to be used for the measurement of pH, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, and Cl<sup>-</sup> in samples of whole blood, serum and plasma.

**Product Name:****OPTI Medical OPTI-CCA Cassettes, OPTI-R Cassettes, OPTI-LION Cassettes****Description:**

The OPTI Medical OPTI-Type Cassettes have sensors for the measurement of the following parameters:

Description	Parameters Measured
OPTI-CCA, B Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , tHb, SO <sub>2</sub>
OPTI-CCA, E Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , tHb, SO <sub>2</sub>
OPTI-CCA, E-Ca Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , tHb, SO <sub>2</sub>
OPTI-CCA, E-Cl Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , tHb, SO <sub>2</sub>
OPTI-CCA, E-Glu Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Glu, tHb, SO <sub>2</sub>
OPTI-CCA, E-BUN Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , BUN, tHb, SO <sub>2</sub>
OPTI-R, E-Ca50 Type	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , tHb, SO <sub>2</sub>
OPTI-LION, E-Plus Type	pH, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup>

List continued on page 3

**Product Name:****OPTI-Check**

## Description:

The OPTI-Check assayed control material is intended for use as a control to monitor the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, tHb and SO<sub>2</sub> in both the OPTI Medical OPTI-CCA and OPTI Medical OPTI-R products.

**Product Name:****OPTI-Check PLUS**

## Description:

The OPTI-Check Plus assayed control material is intended for use as a control to monitor the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, Glucose, BUN (urea), tHb and SO<sub>2</sub> the OPTI Medical OPTI-CCA products.

**Product Name:****OPTI-Check Lytes**

## Description:

The OPTI-Check Lytes assayed control material is intended for use as a control to monitor the measurement of pH, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, and Cl<sup>-</sup> in the OPTI Medical OPTI-LION products.

**Product Name:****OPTI Medical OPTI-CCA Standard Reference Cassettes**

## Description:

Calibrator Cassette levels 1, 2, and 3 for the OPTI Medical OPTI-CCA Analyzer.

**Product Name:****OPTI Medical OPTI-CCA tHb Calibration Cassette**

## Description:

Total Hemoglobin Calibration Cassette for the OPTI Medical OPTI-CCA Analyzer.

**Product Name:****OPTI Medical OPTI-R Calibration Cassette**

## Description:

Calibration Cassette for the OPTI Medical OPTI-R Analyzer

**Product Name:****OPTI Medical OPTI-LION Standard Reference Cassettes**

## Description:

Calibrator Cassette levels 1, 2, and 3 for the OPTI Medical OPTI-LION Analyzer.

**Product Name:****OPTI Medical OPTI-LION Calibration Cassette**

## Description:

Calibration Cassette for the OPTI Medical OPTI-LION Analyzer

**Product Name:****OPTI Medical OPTI-CCA Analyzer, OPTI-R Analyzer, OPTI-LION Analyzer Calibration Gas**

## Description:

Calibration Gas Bottle for the OPTI Medical OPTI-CCA, OPTI-R, and OPTI-LION Analyzers.

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**Product Name:****OPTI Medical OPTI-CCA Analyzer External Power Supply (Battery)**

Description:

External Power Supply (Battery) for the OPTI Medical OPTI-CCA Analyzers.

**Product Name:****OPTI Medical OPTI-R Syringe Adapters**

Description:

Syringe Adapters (for samples) for the OPTI Medical OPTI-R Analyzer.

**Product Name:****OPTI Medical OPTI-R Fluid Pack**

Description:

Reagent Pack for the OPTI Medical OPTI-R Analyzer.

**Product Name:****OPTI Medical ComfortSampler with Accessories**

Description:

Arterial Blood Sampling Kit used for the collection of Whole Blood.

**End of Product List**