MED CERT

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

CNOGA Medical Ltd.
22 Ha-Ilan, North Industrial Park
Or-Akiva, 3065101 – Israel

has introduced and applies a Quality Management System in the area of

Design and development, production and distribution of non-invasive monitors for

- **SpO_2**
- **pCO_2**
- **pO_2**
- **MAP**
- **heart rate**
- **blood ph**
- **blood pressure**
- **hematocrit**
- **cardiac output**
- **haemoglobin**
- **glucose**

Distribution of invasive blood glucose monitors

A Quality Audit demonstrated compliance of the Quality Management System with

EN ISO 13485:2012 + AC:2012

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given standard.
The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 22 September 2018
Hamburg, 20 May 2014

Process No.: QS - 6019
Certificate No.: 6019GB438140520

MEDCERT Certification Body
(Markus Bianchi)

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.99.02-46

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

CNOGA Medical Ltd.
22 Ha-Ilan, North Industrial Park
Or-Akiva, 3065101 – Israel

has introduced and applies a Quality Management System
for the products / product categories

Non-invasive monitors for

- **SpO_2**
- **pCO_2**
- **pO_2**
- **MAP**
- **heart rate**
- **blood ph**
- **blood pressure**
- **hematocrit**
- **cardiac output**
- **haemoglobin**
- **glucose**

An Audit demonstrated compliance of the Quality Management System with

Annex II
excluding section (4)

of the **Council Directive 93/42/EEC concerning Medical Devices**.

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 22 September 2018
Hamburg, 27 May 2014

MEDCERT Certification Body
(Markus Bianchi)

Process No.: QS - 6019
Certificate No.: 6019GB410140527
MEDCERT Identification No.: 0482

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13