

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 652481**  
Issued To: **Coala-Life AB**  
**Kålsängsgränd 10B**  
**75319 Uppsala**  
**Sweden**

In respect of:

**Design and manufacture of cardiac heart monitor and associated software.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-11-01**

Date: **2021-02-08**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

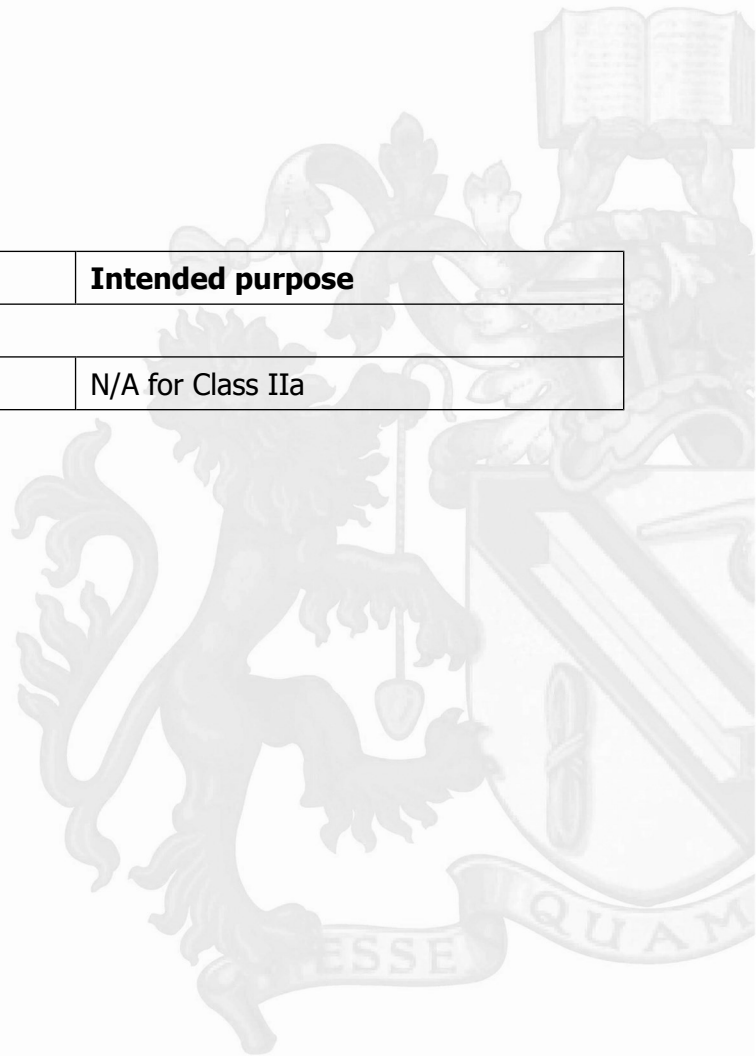
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## Supplementary Information to CE 652481

Issued To:

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NBOG code(s)	Device description	Intended purpose
<b>Class IIa</b>		
MD 1302	Coala Heart Monitor	N/A for Class IIa



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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**75319 Uppsala**  
**Sweden**

**Subcontractor:**

**Service(s) supplied**

Innokas Yhtymä Oy  
Paneeli 2  
EE-11415 Tallinn  
Estonia

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 652481**  
 Date: **2021-02-08**  
 Issued To: **Coala-Life AB  
 Kålsängsgränd 10B  
 75319 Uppsala  
 Sweden**

Date	Reference Number	Action
01 November 2016	8506770	First Issue.
25 February 2019	8892332	Traceable to NB 0086.
17 March 2020	3061941	Add new critical subcontractor Coala Life (Uppsala). Replace subcontractor Enics Sweden with Innokas Yhtymä Oy. Add device table.
29 December 2020	3168649	Change legal manufacture address from 'Riddargatan 18, Stockholm 114 51, Sweden' to 'Kålsängsgränd 10B, 75319 Uppsala, Sweden' Remove critical subcontractor: 'Coala-Life AB, Dag Hammarskjölds Väg, 34B 752 37 Uppsala'
Current	3342935	Certificate renewal.