

# EC CERTIFICATE

Number: 2187930CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**CART-Tech B.V.**

**Padualaan 8  
3584 CH Utrecht  
The Netherlands**

For the product category(ies)

**Cardiac imaging processing software for the area of treatment planning and guidance of minimally invasive cardiovascular interventions**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

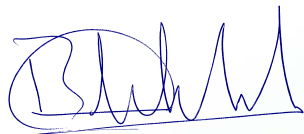
Documents, that form the basis of this certificate:

**Certification Notice 2187443CN, initially dated 17 February 2017  
Addendum, initially dated 17 December 2017**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2024  
Issued for the first time: 17 December 2017  
Reissued: 4 March 2019

DEKRA Certification B.V.



**B.T.M. Holtus**  
Managing Director



**J.A. van Vugt**  
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
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# ADDENDUM

Belonging to certificate: 2187930CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Cardiac imaging processing software for the area of treatment planning and guidance of minimally invasive cardiovascular interventions

Issued to:

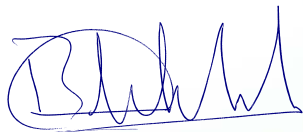
**CART-Tech B.V.**  
Padualaan 8  
3584 CH Utrecht  
The Netherlands

This certificate covers the following product(s):

CARTBox2 version 2.x  
CARTBox Suite Version 3.x

Initial date: 17 December 2017  
Revision date: 11 October 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt  
Certification Manager

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