

# CERTIFICATE

Number: 2115828CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Advanced Medical Diagnostics s.a.**

Waterloo Office Park

Bat I, Bte 3

Drève Richelle, 161

1410 Waterloo, Brussels

Belgium

For the product category:

**Diagnostic HistoScanning systems for tissue differentiation, characterization and visualization to support ultrasonic evaluations**

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 2115828CN, initially dated 22 December 2008**  
**Addendum, initially dated 22 December 2008**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II, section 4 is mandatory. The necessary information 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 2015  
Issued for the first time: 22 December 2008  
Reissued: 1 January 2012

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2115828CE01

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Diagnostic HistoScanning systems for tissue differentiation, characterization and visualization to support ultrasonic evaluations

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Belgium**

This certificate covers the following product(s):

Model HistoScanning version 2.x - indication for prostates

Initial date: 22 December 2008  
Revision date: 28 October 2009

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
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