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DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference number: 2085393CE01, delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in Annex V, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers ‘AGE Reader mu’ systems as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

DiagnOptics Technologies BV
Aarhusweg 4-9
Groningen
The Netherlands

Groningen, 05-12-2013

B.A. van den Berg
Managing Director

Annex: Product list *(document identification)*

Annex to the Declaration of Conformity (Product list)

PRODUCT LIST

'AGE Reader mu' system

This product list belongs to the Declaration of Conformity identified by DI-C-01-005.2 and specifies the CE marked products concerned that DiagnOptics Technologies BV intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The following list identifies the products by name and type and by serial number.

Product name	*Product code*	*Time related information*
'AGE Reader mu'	DMU00100	from serial number: 10000001

Groningen, 05-12-2013

B.A. van den Berg
Managing Director