intertek
Total Quality. Assured.

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

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

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Agfa NV

Main Site: Septestraat 27, 2640 Mortsel, Belgium

Product Category:

- Software for imaging, radiology and clinical information
- Devices for general radiology, mammography, extremities diagnostics and radiotherapy imaging, including oncology, neurology and cardiology

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41376838

Initial Certification Date:
July 1, 2018

Certificate Valid from:
July 1, 2018

Certificate Expiry Date:
July 1, 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

15 June 2018
Signed Date

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.