

EC Certificate Full Quality Assurance System: ES10/77504

The management system of

Alma IT Systems, S.L.

Passeig de Gràcia, 11, Escalera A, 2º 1ª
08007 Barcelona, Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 15 May 2018 until 14 May 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 28 April 2021
Issue 7. Certified since 15 May 2009

Certification is based on reports numbered ES/MAD 127837

Authorised by

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EC Certificate Full Quality Assurance System: ES10/77504, continued

Alma IT Systems, S.L.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

Medical Imaging Software ALMA3D for analyzing medical digital images of X-ray radiography, Computed Tomography, Magnetic Resonance or Ultrasounds comprising of 15 modules of visualisation:

- Alma 2D MAMMO
- Alma 2D VIEWER
 - Alma 2D CLINIC
 - Alma 2D Lite CD
- Alma 2D mCLINIC
 - Alma 2D 365
 - Alma 2D ORTHO
 - Alma 2D iCLINIC
 - Alma 2D PRINT
- Alma 2D Web Platform
- Alma 3D NUCLEAR
- Alma 3D DENTAL
- Alma 3D VOLUME
- Alma 3D VASCULAR
 - Alma 3D MPR
 - Alma 3D CARDIO

Software de imagen médica ALMA 3D para el análisis de imágenes digitales médicas incluyendo estos formatos: Rayos X, Tomografía Computarizada, Resonancia Magnética y Ecografía compuesto por 15 módulos:

- Alma 2D MAMMO
- Alma 2D VIEWER
 - Alma 2D CLINIC
 - Alma 2D Lite CD
 - Alma 2D 365
- Alma 2D mCLINIC
 - Alma 2D ORTHO
 - Alma 2D iCLINIC
 - Alma 2D PRINT
- Alma 2D Web Platform
- Alma 3D NUCLEAR
- Alma 3D DENTAL
- Alma 3D VOLUME
- Alma 3D VASCULAR
 - Alma 3D MPR
 - Alma 3D CARDIO

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market