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EC Certificate Full Quality Assurance System:
Certificate ES19/86774

The management system of

Alma IT Systems, S.L.

Carrer del Mestre Dalmau, 19
08031 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 06 May 2021 until 14 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 15 May 2009.

Certification is based on reports numbered ES/BCN 127837

Authorised by

Global Medical Devices Head of Notified Body

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Alma IT Systems, S.L.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Medical Imaging Software Alma WORKSTATION for analysing medical digital images of X-ray radiography, Computed Tomography,Magnetic Resonance or Ultrasounds comprising of 14 modules of visualisation:

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

Medical Imaging Software SIGMA for the dental implantology professionals for visualizing and analyzing medical digital images in 2 and 3 dimensions.

Software de imagen médica Alma WORKSTATION para el análisis de imágenes digitales médicas incluyendo estos formatos: Rayos X, Tomografía Computarizada, Resonancia Magnética y Ecografía compuesto por 14 módulos:

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

Software de imagen médica SIGMA para los profesionales de la implantología dental para la visualización y análisis de imágenes digitales médicas en 2 y 3 dimensiones.

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.