The ALS Con-Tel II system is a complex system that allows clinical monitoring in the home of the patient, and is comprised of two structural elements:

- **ALS Con-Tel II**: a home electromedical device.
- **ALS Gate**: a dedicated Web portal used to consult and assess captured clinical parameters.

**ALS Con-Tel II**

This is an active medical device which depends on a power source for operation, and is used either alone or in combination with other medical devices.

Its main feature is to provide physicians or healthcare professionals with all information concerning analysis, early diagnosis, monitoring or treatment of clinical conditions, health, diseases, or birth defects.

**Certification**

For medical devices, there are legislative provisions dictating that technologies should be designed, built, maintained and operated effectively, efficiently and – most of all – safely.

ALS Con-Tel II is built to the requirements of the laws and directives in force, and is provided with the EC051 mark (complete Quality Assurance System)(Fig. 1).

**Reference Framework – System Standards**


**Reference Framework – Product Standards**

- EN 60601-1 General Safety Standards 12 - 1998
- CEI EN 60601-1-4 General Requirements - Programmable Electrical Medical Systems
- UNI EN 865 2000 Pulse Oxymeters - Special Requirements
Requirements Collateral Standard: Electromagnetic Compatibility-
Requirements and Testing
- UNI CEI EN ISO 14971 Application of Risk Management to Medical Devices
- EN 980 Graphical Symbols for Use in the Labelling of Medical Devices
- EN 1041 Information Supplied by the Manufacturer with Medical Devices

Reference Framework – Laws
- 89/336 EEC Electromagnetic Compatibility
- Presidential Decree No. 224 dated 24.05.1988 Liability for Damages Due to Defective Products
- Legislative Decree No. 115 dated 17/3/1995 General Product Safety

The risk analysis for this device was performed according to the criteria as set forth in Standard EN 14971.
Because of its characteristics, “it is not a life-saving device, and it may not be used for emergency”.

Features
ALS Con-Tel II is a modular medical device which makes it possible to quantitatively and non-invasively assess oxygen saturation in arterial haemoglobin. It also