

19 Certificates

EC CERTIFICATE

Certificate No 1104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

A.M.I. ITALIA SRL

manages in the factories of:

QUARTO (NA) - VIA CUPA REGINELLA 17/A (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

Semiautomatic and manual semiautomatic external cardiac defibrillator

Type ref. SAVER-ONE; SAVER-ONE-P; SAVER-ONE-D

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AI00006; 10AJ00117.

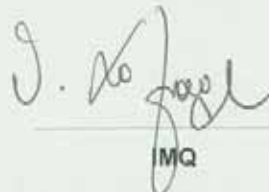
This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.

Notified Body notified to European Commission under number: 0051.

Date: 2008-02-18

Updated: 2009-07-27

Substitution Date: 2008-02-18


IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2013-02-17 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts



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