

EC CERTIFICATE

Certificate No 1104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

A.M.I. ITALIA SRL

80143 NAPOLI (NA) - CENTRO DIREZIONALE ISOLA A7 (ITA) - Italy

manages in the factories of:

80010 QUARTO (NA) - VIA CUPA REGINELLA 17/A (ITA) - Italy

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - ROZSA UTCA 16 (HUN) - Hungary

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

Semiautomatic and manual semiautomatic external cardiac defibrillator

Type ref. SAVER ONE P; SAVER ONE D

Automatic and semiautomatic external cardiac defibrillator

Type ref. SAVER ONE.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos: 10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018; 10AO00009.

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

Notified Body notified to European Commission under number: 0051.

Date: 2008-02-18

Updated: 2014-03-18

Substitution Date: 2013-04-15


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 2018-02-17 (article 11, clause 11 of the Directive).

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