

EC CERTIFICATE

Certificate No 954/MDD

Production Quality Assurance System Approval Certificate

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

EF MEDICA SRL

manages in the factories of:

EGNA (BZ) - VIA F. ORTLER 3 (ITA) - Italy

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

Recording charts for medical equipment

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC.

Reference to IMQ files Nos: 10AG00125.

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: 2006-07-26

Luca Bronckert
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"

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



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*Giuseppe
A. Polverini*

EC SERTIFIKATAS

Sertifikato Nr. 954/MDD

Kokybės užtikrinimo sistemos sertifikatas

Remiantis direktyva 93/42/EEC ir 1997-02-24 įstatyminio dekreto Nr. 46 V priedo 3 skyriumi pažymime, kad

EF MEDICA SRL

adresu

EGNA (BZ) – VIA F. ORTLER 3 (ITA) – Italy

šių produktų -

medicininės įrangos diagraminis popierius -

atitikimą garantuojanti kokybės užtikrinimo sistema atitinka esmines nacionalinio įstatyminio dekreto ir direktyvos 93/42/EEC nuostatas.

IMQ Nr.: 10AG00125

Šį sertifikatą išdavė IMQ S.p.A. kaip notifikuoti įstaiga, veikianti pagal direktyvos 93/42/EEC nuostatas.

Notifikuoti įstaiga notifikuota Europos komisijai Nr. 0051.

Data: 2006-07-26

IMQ /parašas/

Aprobuotas sertifikatas įrodo, kad „Medicinos prietaisų EC sertifikavimo normos atitinka direktyvos 93/42/EEC nuostatas“.

