EC CERTIFICATE

Certificate No 094/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:

KORPO SRL

16121 GENOVA (GE) - VIA XX SETTEMBRE 3/28 (ITA) - Italy

manages in the factories of:

16121 GENOVA (GE) - VIA XX SETTEMBRE 3/28 (ITA) - Italy

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

Electrosurgical unit
Type ref. TIMED TD 50A Micropulse e relativi accessori

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. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10S9700026 ; 10S9700027 ; 10S9700028; 10EL00022; 10EN00071; DM17-0019151.

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:	1998-09-30
Updated:	2018-05-03
Substitution Date:	2013-09-15
Expiry Date:	2023-05-02

IMQ

cosign

ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

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