EC CERTIFICATE

Certificate No 1203/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V 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:

Elastic non-absorbable surgical thread attached to atraumatic needles

Type ref. Elasticum (REF. E3.5 J1.3 R115; E4 J1.3 R115; E3.5 J1.5 R165; E3.5 C3/8; E2.5 C3/8; E5 J2.0 R350)

with relevant essential requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V. For class IIb devices, this certificate is valid only with the relevant certificate of Annex III.

Reference to IMQ files Nos: 10AI00221; 10EL00022; 10EN00027; DM14E0336731-01.

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: 2009-02-17
Updated: 2014-11-20
Substitution Date: 2013-03-28

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 2018-03-27 (article 11, clause 11 of the Directive).

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