

EC CERTIFICATE

Certificate No 2028/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 factory 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. E3.5J1.3R115; E4J1.3R115; E3.5J1.5R165; E3.5C3/8; E2.5C3/8; E5J2.0R350 Trade mark Elasticum

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 and III devices, this certificate is valid only with relevant EC Type-Examination certificate of Annex III.

Reference to IMQ files Nos:

DM19-0037035-01.

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.



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