

EC CERTIFICATE

Certificate No 839/MDD

Full Quality Assurance System Approval Certificate

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

GVS SPA

40069 ZOLA PREDOSA (BO) - VIA ROMA 50 (ITA) - Italy

manages in the factories of:

40069 ZOLA PREDOSA (BO) - VIA ROMA 50 (ITA) - Italy

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

Sterile infusion set and accessories

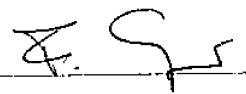
Type ref. As to document CAP 05 Rev. 6 dated 07.10.2010 annex to Technical File set ed extension line; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).

Reference to IMQ files Nos: 10AE00197; 10AG00180; 10AH00183; 10AH00200; 10AH00273; 10AK00140.

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: 2005-05-20
Updated: 2010-11-05
Substitution Date: 2008-01-22


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 2015-11-04 (article 11, clause 11 of the Directive).

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

