

# EC CERTIFICATE

Certificate No 839/MDD

## Full Quality Assurance System Approval Certificate

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

### GVS SPA

manages in the factories of:

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 FT.SINF.01/B01 rev. 04 dated 10.12.2007; valid only if provided by IMQ stamp.

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

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

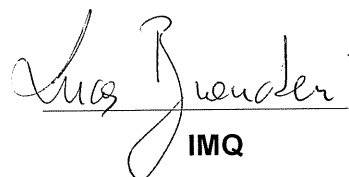
This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.

Notified Body notified to European Commission under number: 0051.

Date: 2005-05-20

Updated: 2008-01-22

Substitution Date: 2007-10-10

  
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 2010-05-19 (article 11, clause 11 of the Directive).

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

