EC CERTIFICATE

Certificate No 914/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:

FASET SRL

20090 TREZZANO SUL NAVIGLIO (MI) - VIA GOLDONI 13 (ITA) - Italy

manages in the factories of:

20090 TREZZANO SUL NAVIGLIO (MI) - VIA C. GOLDONI 13 (ITA) - Italy

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

Nebulizers and inhaler

Type ref. 129; 129a; 127; 127a; 126; 126a; 131; 131a; 117; 117a; 116; 116a; 115; 115a; 104; 102; 121H; 121A; 120; 120a; 730; 740; 750

Equipment for endotympanic insufflation

Type ref. 727; 728; 729

Medical and surgical suction equipment

Type ref. 213; 208; 220; 205; 205a; 205s; 205as; 209; 209a; 209s; 209as; 211; 211s; 217; 217a; 217s; 217as; 225; 225a; 225s; 225as; 206; 206a; 221; 221s; 222; 222a; 204; 234; 203; 233; 218; 231; 219; 600v; 600; 601v; 601; 602v; 603v; 605v; 606; 606v; 607; 608v; 609; 609v; 621

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

Reference to IMQ files Nos: 10AG00035, 10AL00002; 10EL00042.

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: 2006-03-29
Updated: 2011-06-27
Substitution Date: 2011-02-22

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 2016-02-21 (article 11, clause 11 of the Directive).

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

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