

# EC CERTIFICATE

Certificate No 1641/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

### Ingeniería y Técnicas Clínicas S.A.

28500 Arganda del Rey (Madrid) - C/Tungsteno 11-13 (ESP) - Spain

manages in the factories of:

28500 Arganda del Rey (Madrid) - C/Tungsteno 11-13 (ESP) - Spain

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

#### Medical supply units

Type ref. Classic; Vertical; Claire; Carril Tecnico; Nexus LT; Nexus LM; Nexus LX  
Trade mark ITC

#### Nitric oxide monitor and dosing system

Type ref. NOXtec 1000; NOXtec 2000; NOXtec 3000.  
Trade mark ITC

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos:

10AN00131; DM16-0007596-01; DM16A0668657-01.

**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: 2014-01-15  
Updated: 2017-03-03  
Substitution Date: 2017-02-14  
Expiring Date: 2022-02-13



IMQ



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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".

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