



## 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 11-15 (ESP) - Spain

manages in the factory of:

28500 Arganda del Rey (Madrid) - C/Tungsteno 11-15 (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

#### Device for monitoring of the oxygen flow rate and of the compliance in long-term oxygen therapy

Type ref. VisionOx SL; VisionOx ML; VisionOx XL  
Trade mark VisionOx

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. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AN00131; DM16-0007596-01; DM16A0668657-01; DM18-0033394-01; DM18-0033860-01; DM20-0047867-01; DM20-0056301-01; DM21-0062489-01.

**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  
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