

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60034869 0001

Report No.: 28300149 002

Manufacturer: Sibel S.A.
500 Bajos, Rosellon St.
08026 Barcelona
Spain

Scope: Design/development and production of
respiratory measurement devices

Date of Expiry: 08.10.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notif

Date 22.09.2011

Dipl.

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. **CE**