TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60133106 0001

Report No.: 28300339 006

Manufacturer:
SIBEL S.A.U.
Rosellón 500, Bajos
08026 Barcelona
Spain

Products:
- Respiratory measurement devices
- Sleep related breathing disorder treatment devices

(see attachment for site included)
Replaces Certificate, Registration No.: HD 60104898 0001

Expiry Date: 2023-10-08

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-11-20

Date: 2018-11-20

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133106 0001
Report No.: 28300339 006

Manufacturer: SIBEL S.A.U.
Rosellón 500, Bajos
08026 Barcelona
Spain

Site included:

SIBEL S.A.U.
Avda Maria Zambrano
31 Edificaio Wtcz Torre Oeste Planata
15-50018 Zaragoza
Spain

Activity: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Date: 2018-11-20

Sebastian Miniszek