

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1000175-1


Organization: SIBEL S.A.U.
Rossellón, 500 Bajos
08026 Barcelona
Spain

Scope: Design and development, manufacture, distribution and servicing of devices for respiratory measurement and sleep related breathing disorder treatment.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92641076-40
Effective date: 2021-12-16
Expiry date: 2024-10-08
Issue date: 2021-12-16




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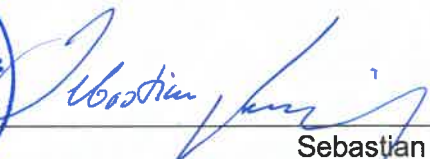
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08026 Barcelona
Spain

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	SIBEL S.A.U. Rosselló, 500 bajos 08026 Barcelona Spain	Design and development, production, distribution and servicing of devices for respiratory measurement and sleep related breathing disorder treatment.
/02	SIBEL S.A.U. Raimon Casellas 6-8 Polígon Industrial Unitat Hermética 08205 Sabadell (Barcelona) Spain	Product preservation/ Warehouse.
/03	SIBEL S.A.U. Avda Maria Zambrano 31 Edificacio Wtcz Torre Oeste Planta 1550018 Zaragoza Spain	Design and development of software for respiratory measurement and sleep related breathing disorder treatment. Customer service.

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