Certificate CH13/0455.00



The management system of

## Lauener et Cie SA

Route de l'Europe 11 CH - 2017 Boudry

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 18 April 2022 until 17 April 2025 and remains valid subject to satisfactory surveillance audits.

Recertification audit due a minimum of 60 days before the expiration date.

Issue 9. Certified since 18 April 2013

This is a multi-site certification. Additional site details are listed on subsequent pages.

Authorised by



SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421 M2

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Certificate CH13/0455.00, continued

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## Lauener et Cie SA

ISO 13485:2016 EN ISO 13485:2016



Issue 9

Detailed scope

#### Main and legal Site (Switzerland):

•Manufacturing of non-sterile mechanical components for surgical instruments.

•Subcontracting in manufacturing and assembly of non-sterile mechanical components for implantable and not implantable medical devices.

### Additional facility (Portugal):

Quality control activities (Visual control and inspection by attributes) on non-sterile mechanical components for implantable and not implantable medical devices

Additional facilities

Lauener et Cie SA Route de l'Europe 11 CH - 2017 Boudry

Lauener et Cie SA Zona Industrial De Felgueiras PT - 4550-161 Castelo De Paiva



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