

Certificate BE17/819942823

The management system of

**Surgi-Tec N.V.**

**SGS**

Poortakkerstraat 43, BE-9051 Sint-Denijs-Westrem, Belgium

has been assessed and certified as meeting the requirements of

**ISO 13485:2016/EN ISO 13485:2016**

**Medical devices - Quality management systems - Requirements for regulatory purposes**

For the following activities

**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 29 July 2026 until 03 July 2029 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 15 October 2018

Last certificate expiry date 03 July 2029

Recertification audit date 01 August 2025

Authorised by

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## ISO 13485:2016/EN ISO 13485:2016

### Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 8

Design, development, manufacture and sales of sterile and non-sterile titanium

-Distraction devices intended for the distraction osteosynthesis of the craniofacial skeleton

-Anchoring devices intended to be implanted intraorally and used as an anchor for orthodontic procedures

-Osteosynthesis screws

Design, development, manufacture and sales of non-sterile reusable surgical instruments dedicated to cranio-maxillo-facial surgery

Design, development, manufacture and sales of non-sterile instruments dedicated to cranio-maxillo-facial surgery.

Distribution of medical devices dedicated to cranio-maxillo-facial surgery.

Contract manufacture of non-sterile metal implants dedicated to cranio-maxillo-facial-surgery.

Contract manufacture of non-sterile metal and thermoplastic surgical instruments dedicated to cranio-maxillo-facial-surgery.

Contract manufacture of metal based components for medical device industry using precision machining, CNC turning and milling



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