

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

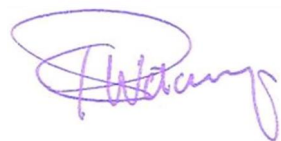
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 21 July 2026 until 03 July 2029 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 15 October 2018

Last certificate expiry date 03 July 2026

Recertification audit date 01 August 2025



Authorised by

Pieter Weterings

Certification Manager

SGS BELGIUM NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - [www.sgs.com](http://www.sgs.com)



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions | SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



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

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

Issue 7

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
- Osteosynthesis plates intended for the fixation of the segments after zygoma, maxillary, mandibular and chin osteotomies and fixation of the segments after trauma in orthognathic and ortho-facial surgery.

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



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

