

Certificate BE17/819942823

The management system of

# Surgi-Tec N.V.

Poortakkerstraat 43, 9051 Sint-Denijs-Westrem, Belgium

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

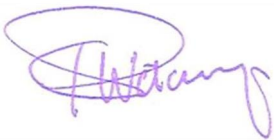
**EN ISO 13485:2016**

For the following activities

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

This certificate is valid from 18 September 2025 until 03 July 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 15 October 2018



Authorised by

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# Surgi-Tec N.V.

## ISO 13485:2016 EN ISO 13485:2016

Issue 6

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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