

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

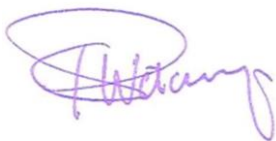
ISO 13485:2016

EN ISO 13485:2016

For the following activities

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

This certificate is valid from 14 July 2023 until 03 July 2026 and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 15 October 2018.



Authorised by
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Certification Manager

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Surgi-Tec N.V.

ISO 13485:2016 EN ISO 13485:2016

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.



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