

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 17 July 2020 until 16 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 15 October 2018.
Recertification audit due before 17 June 2023.

Authorised by

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Certification Manager

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Accreditation Number

005-QMS
EN ISO/IEC 17021-1:2015



Surgi-Tec N.V.

ISO 13485:2016
EN ISO 13485:2016



Issue 3

Detailed scope

Design, development, manufacture and sales of 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 fractures, corrective osteotomies, bridging of load-bearing bone segments and reconstructive procedures to the facial skeleton in orthognathic and orthofacial 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.



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