

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 05/04/2019 until 14/10/2021  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22/09/2020

Issue 2. Certified since 15/10/2018

Authorised by

Pieter Weterings  
Certification Manager

SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com



Accreditation Number  
005 QMS

Page 1 of 2



# Surgi-Tec N.V.

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



Issue 2

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.**



Accreditation Number  
005 QMS

