EC Certificate Full Quality Assurance System: Certificate BE19/819943360

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 09/05/2019 until 14/10/2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 05/04/2019.
Re certification audit due before 22/09/2020.

Certification is based on reports numbered BE/AMD 16/1273.QMD

Authorised by

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The management system of

Surgi-Tec N.V.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Non-sterile titanium distraction devices intended for the distraction osteosynthesis of the craniofacial skeleton
- transpalatal distractor (classic, all-in-one, neo)
- transmandibular distractor

Non-sterile titanium anchoring devices intended to be implanted intraorally and used as an anchor for orthodontic procedures
- ortho bone anchor Mommaerts (hooks, hooks and bracket, hooks and tube)
- ortho bone anchor Surgi-Tec (mandibula and maxilla)

Non-sterile titanium osteosynthesis screws
- self drilling intended for fixation of distraction osteosynthesis systems and skeletal anchorage systems
- self tapping intended for fixation of distraction osteosynthesis systems, skeletal anchorage systems and osteosynthesis plates
- micro intended for fixation of bone grafts

Non-sterile titanium 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.