EU Quality Management System Certificate BE24/00000296

The management system of

Surgi-Tec N.V.

Poortakkerstraat 43, 9051 Sint-Denijs-Westrem, Belgium

SRN Number: BE-MF-000000257

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 21 March 2025 until 27 November 2029 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 27 May 2029

Issue 2. Certified since 27 November 2024

Authorised by
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Certification Manager

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Surgi-Tec N.V.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class Ir devices

MDN1208 MDS1005 MDS1006

Non-sterile reusable surgical instruments dedicated to cranio-maxillo-facial surgery
(Basic UD-DI: 540700775CHINST6V)

Class IIb devices

MDN1102 MDS1005
EMDN: P01020101

Non-sterile and sterile titanium distraction devices intended for the distraction osteosynthesis of the craniofacial skeleton:
- TransPalatal Distractor (TPD) Classic
- TransPalatal Distractor (TPD) All-in-one
- TransPalatal Distractor (TPD) Neo
(Basic UDI-DI: 540700775DISEQ)

EMDN: P010201

Non-sterile and sterile titanium anchoring devices intended to be implanted intraorally and used as an anchor for orthodontic procedures: Ortho bone anchors (OBA)
- OBA SLA
- OBA Maxilla
- OBA Mandible
(Basic UDI-DI: 540700775OBAEN)

Osteosynthesis screws (OS) used in Cranio-Maxillo Facial surgery
Sterile and nonsterile 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
(Basic UDI-DI:540700775OSRH)

Osteosynthesis plates (OSP)
Non-sterile and sterile titanium 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 orthofacial surgery
(Basic UDI-DI: 540700775OSPH7)

EU Quality Management System Certificate BE24/00000296, continued

Surgi-Tec N.V.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - BE/AMD/6/1273.QMD - S2A 3.1 + TFR 1.1 + CTC
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: Addition of Class IIb (WET) devices to certificate scope (QMS) as TFR is concluded