EU Technical Documentation Assessment Certificate
BE24/00000300

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 Technical Documentation certificate (Annex IX Chapter II)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 28 November 2024 until 28 November 2029 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 28 May 2029

Issue 1. Certified since 28 November 2024

Authorised by
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Global Medical Device
Certification Manager
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SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

EU Technical Documentation Assessment Certificate
BE24/00000300, continued

Surgi-Tec N.V.

MDR (EU) 2017/745 Technical Documentation certificate (Annex IX Chapter II)

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)

Conditions for & limitation to the validity of the certificate:
For placing on the market of devices covered by this certificate, an EU Quality Management System Certificate according to Annex IX is required.

List of examinations and tests performed, which may include reference to relevant CS and harmonized 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 - TFR 1.1
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

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)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 27 November 2024 until 27 November 2029 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 27 May 2029

Issue 1. Certified since 27 November 2024

Authorised by
Virginie Siloret
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EU Quality Management System Certificate BE24/00000296, continued

Surgi-Tec N.V.

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

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)

Class Ir devices

MDN1208 MDS1005 MDS1006

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

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
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

Surgi-Tec N.V.
Poortakkerstraat 43
9051 Sint-Denijs-Westrem
Belgium

24th August 2023

Confirmation Letter Reference: CLNB1639 - BE/AMD/6/1273.QMD

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Surgi-Tec N.V.
Poortakkerstraat 43
9051 Sint-Denijs-Westrem
Belgium
SRN Number: BE-MF-000000257

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Device 1 540700775DISEQ Non-sterile titanium distraction devices intended for the distraction osteosynthesis of the craniofacial skeleton - transpalatal distractor (classic, all-in-one, neo)	Class IIb implantable non- WET device	N/A	BE19/819943360, Issue 2, NB1639

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Device 2 540700775OBAEN Non-sterile titanium anchoring devices intended to be implanted intraorally and used as an anchor for orthodontic procedures - ortho bone anchor Mommaerts (hooks) - ortho bone anchor Surgi-Tec (mandibula and maxilla)	Class IIb excluding Class IIb implantable non-WET	N/A	BE19/819943360, Issue 2, NB1639
Device 3 540700775OSRH 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	Class IIb excluding Class IIb implantable non-WET	N/A	BE19/819943360, Issue 2, NB1639

Device 4 540700775OSPH7 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.	Class IIb excluding Class IIb implantable non-WET	N/A	BE19/819943360, Issue 2, NB1639

In order, to be consistent with the MDD certificate only the devices mentioned in the MDD certificate are added in the 1st column of the table.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/08/24	Version 1	Initial issue

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

Pieter Weterings
Certification Manager

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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.