

EC DECLARATION OF CONFORMITY

EG Verklaring van overeenstemming met Bijlage VII van het Koninklijk besluit van 18 maart 1999

We, Surgi-Tec NV , Poortakkerstraat 43 - 9051 Sint-Denijs-Westrem, Belgium

Hereby declare under our sole responsibility as manufacturer, that the following CE marked products

Reusable instruments

- Surgi-Tec instrument handle: GMDN-code: 33968
- Surgi-Tec reusable instruments: GMDN-CODE 47829

Have been classified as Class I , according to Annex IX at Directive 93/42/EEC and the last amendment 2007/47/EC on Medical Devices.

Are in conformity with the Essentials Requirements of Directive 93/42/EEC on Medical Devices.

Date : 17/02/2020

Name and function : Karina Scheerlinck, CEO

Signature : 

Attachments

- I. List of products

Attachment 1: List of products

Article code	Description
Surgi-Tec instrument handle: GMDN-code: 33968	
99-901A	Handpiece For All Inserts
Surgi-Tec reusable instruments: GMDN-CODE 47829	
99-101A	Screwdriver - Internal Pentagon
99-906A	Screwdriver - Micro Internal Pentagon
99-906S	Insert - Micro Internal Pentagon
99-907A	Insert - Micro External Pentagon
99-909S	Insert - Internal Pentagon
99-910S	Insert - External Pentagon
99-912S	Screwdriver for angle piece : internal pentag 1,4 mm (for Mini OS)
99-915S	Insert - Slotted