

**EC DECLARATION OF CONFORMITY**

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

**Anchoring devices**

**OBA (Ortho Bone Anchor) Surgi-Tec**  
**OBA (Ortho Bone Anchor) “Mommaerts”**  
*(Article codes attached)*


Have been classified as Class IIb , according to Annex IX, rule 8 of Directive 93/42/EEC on Medical Devices.

Are in conformity with the Essentials Requirements according to Annex II (excluding section 4) of Directive 93/42/EEC on Medical Devices.

Notified body SGS Belgium, identification number 1639, assessed the full quality assurance system according EN ISO 13485:2016 and issued certificate number BE19/819943360 dated 05/04/2019

Date : 11/05/2020

Name and function : Karin Scheerlinck, CEO

Signature : 

<b>REF</b>	<b>DESCRIPTION</b>	<b>BASIC UDI-DI (GTIN)</b>
02-001A	OBA SLA - Short neck - Tube	05407007750016
02-002A	OBA SLA - Short neck - Bracket	05407007750030
02-003S	OBA SLA - Short neck - Double hook	05407007750054
02-004A	OBA SLA - Long neck - Tube	05407007750078
02-005A	OBA SLA - Long neck - Bracket	05407007750092
02-005S	OBA Maxilla - Long neck - Double hook	05407007750115
02-006S	OBA SLA - Long neck - Double hook	05407007750139
02-007A	OBA SLA - Zygoma - Tube	05407007750153
02-007S	OBA Mandible - Long neck - Double hook	05407007750177
02-008A	OBA SLA - Zygoma - Bracket	05407007750191
02-009S	OBA SLA - Zygoma - Double hook	05407007750214
02-021S	OBA Maxilla - Short neck - Straight hook - Left	05407007750238
02-022S	OBA Maxilla - Short neck - Straight hook - Right	05407007750252
02-023S	OBA Maxilla - Long neck - Straight hook - Left	05407007750009
02-024S	OBA Maxilla - Long neck - Straight hook - Right	05407007750283
02-025S	OBA Maxilla - Short neck - Long hook - Left	05407007750306
02-026S	OBA Maxilla - Short neck - Long hook - Right	05407007750320
02-027S	OBA Maxilla - Long neck - Long hook - Left	05407007750344
02-028S	OBA Maxilla - Long neck - Long hook - Right	05407007750368
02-031S	OBA Maxilla Pediatric - Short neck - Long hook - Left	05407007750382
02-032S	OBA Maxilla Pediatric - Short neck - Long hook - Right	05407007750405
02-041S	OBA Mandible - Long neck - Double hook - Left	05407007750467
02-042S	OBA Mandible - Long neck - Double hook - Right	05407007750481
02-043S	OBA Mandible - Long neck - Straight hook - Left	05407007750504
02-044S	OBA Mandible - Long neck - Straight hook - Right	05407007750528
02-045S	OBA Mandible - Long neck - Long hook - Left	05407007750542
02-046S	OBA Mandible - Long neck - Long hook - Right	05407007750566
02-050S	OBA SLA – Zygoma – Long hook	05407007753062