

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

Plates
OSP (Osteosynthesis Plates)

OSP MESH (Osteosynthesis Mesh Plates)
OSP SLOT (Osteosynthesis Slot Plates)
(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 : 

REF	DESCRIPTION	BASIC UDI-DI (GTIN)
60-001S	Slot Plate - SLA - LeFort 1 - Diamond	05407007751099
60-003S	Slot Plate - SLA - LeFort 1 - Ruby	05407007751112
60-004S	Slot Plate - SLA - LeFort 1 - Emerald	05407007751136
60-005S	Slot Plate - SLA - LeFort 1 - Topaz	05407007751150
60-006S	Slot Plate - SLA - LeFort 1 - Amethyst	05407007751174
60-007S	Slot Plate - SLA - Genioplasty - Opal	05407007751198
60-008S	Slot Plate - SLA - Genioplasty - Onyx	05407007751211