

## 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.

### **Distraction devices**

**Trans-Mandibular Distractor (TMD)**  
**Trans-Palatal Distractor (TPD) Classic**  
**Trans-Palatal Distractor (TPD) All-in-one**  
**Trans-Palatal Distractor (TPD) Neo**  
*(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>DISTRACTION DEVICES - TPD</b>		
<b>REFERENCE</b>	<b>DESCRIPTION</b>	<b>BASIC UDI-DI (GTIN)</b>
03-800A	TPD Classic - Left and Right Abutment plates	05407007750719
03-801A	TPD Classic - Module 1	05407007750733
03-802A	TPD Classic - Module 2	05407007750757
99-100S	TPD-All in one / Classic locking screw	05407007752898
03-825A	TPD Classic - Module 2.5	05407007750818
03-803A	TPD Classic - Module 3	05407007750771
03-804A	TPD Classic - Module 4	05407007750795
03-901A	TPD All-In-One - Module 1	05407007750832
03-902A	TPD All-In-One - Module 2	05407007750856
03-925A	TPD All-In-One - Module 2.5	05407007750917
03-903A	TPD All-In-One - Module 3	05407007750870
03-904A	TPD All-In-One - Module 4	05407007750894
03-701A	TPD NEO - Module 1	05407007750597
03-702A	TPD NEO - Module 2	05407007750610
03-725A	TPD NEO - Module 2.5	05407007750665
03-703A	TPD NEO - Module 3	05407007750634

<b>DISTRACTION DEVICES - TMD</b>		
<b>REFERENCE</b>	<b>DESCRIPTION</b>	<b>BASIC UDI-DI (GTIN)</b>
06-131A	TMD Pediatric - Short model	05407007750962
06-132A	TMD Pediatric - Long model	05407007750986
06-141A	TMD Bulky - Short Model	05407007751006
06-142A	TMD Bulky - Long Model	05407007751020
06-241A	TMD Flat - Short Model	05407007751044
06-242A	TMD Flat - Long Model	05407007751068