

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

Screw

OS (Osteosynthesis screw) *(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 : 

Product code	Description	BASIC UDI-DI (GTIN)
70-105S	Ø 2.3 Selftapping Screw - L 5 mm - Round	05407007751235
70-105S.5	Ø 2.3 Selftapping Screw - L 5 mm - Round - 5 Pack	05407007751259
70-107S	Ø 2.3 Selftapping Screw - L 7 mm - Round	05407007751273
70-107S.5	Ø 2.3 Selftapping Screw - L 7 mm - Round - 5 Pack	05407007751297
70-205S	Ø 2.3 Selftapping Screw - L 5 mm - low Pentagon	05407007751310
70-205S.5	Ø 2.3 Selftapping Screw - L 5 mm - low Pentagon - 5 Pack	05407007751334
70-207S	Ø 2.3 Selftapping Screw - L 7 mm - low Pentagon	05407007751358
70-207S.5	Ø 2.3 Selftapping Screw - L 7 mm - low Pentagon - 5 Pack	05407007751372
70-217S	Ø 2.3 Selftapping Screw - L 17 mm - low Pentagon	05407007751396
70-217S.5	Ø 2.3 Selftapping Screw - L 17 mm - low Pentagon - 5 Pack	05407007751419
70-219S	Ø 2.3 Selftapping Screw - L 19 mm - low Pentagon	05407007751433
70-219S.5	Ø 2.3 Selftapping Screw - L 19 mm - low Pentagon - 5 Pack	05407007751457
70-221S	Ø 2.3 Selftapping Screw - L 21 mm - low Pentagon	05407007751471
70-221S.5	Ø 2.3 Selftapping Screw - L 21 mm - low Pentagon - 5 Pack	05407007751495
70-505S	Ø 2.0 Selfdrilling Screw - L 5 mm - Round	05407007751518
70-505S.5	Ø 2.0 Selfdrilling Screw - L 5 mm - Round - 5 Pack	05407007751532
70-507S	Ø 2.0 Selfdrilling Screw - L 7 mm - Round	05407007751556
70-507S.5	Ø 2.0 Selfdrilling Screw - L 7 mm - Round - 5 Pack	05407007751570
70-605S	Ø 2.0 Selftapping Screw - L 5 mm - Round	05407007751594
70-605S.5	Ø 2.0 Selftapping Screw - L 5 mm - Round - 5 Pack	05407007751617
70-607S	Ø 2.0 Selftapping Screw - L 7 mm - Round	05407007751631
70-607S.5	Ø 2.0 Selftapping Screw - L 7 mm - Round - 5 Pack	05407007751655
70-609S	Ø 2.0 Selftapping Screw - L 9 mm - Round	05407007751679
70-609S.5	Ø 2.0 Selftapping Screw - L 9 mm - Round - 5 Pack	05407007751693
70-611S	Ø 2.0 Selftapping Screw - L 11 mm - Round	05407007751716
70-611S.5	Ø 2.0 Selftapping Screw - L 11 mm - Round - 5 Pack	05407007751730
70-707S	Ø 2.0 Selfdrilling Screw - L 7 mm - Pentagon	05407007751754
70-707S.2	Ø 2.0 Selfdrilling Screw - L 7 mm - Pentagon - 2 Pack	05407007751778
70-707S.5	Ø 2.0 Selfdrilling Screw - L 7 mm - Pentagon - 5 Pack	05407007751792
70-709S	Ø 2.0 Selfdrilling Screw - L 9 mm - Pentagon	05407007751815
70-709S.5	Ø 2.0 Selfdrilling Screw - L 9 mm - Pentagon - 5 Pack	05407007751839
70-805S	Ø 2.3 Selftapping Screw - L 5 mm - Pentagon	05407007751853
70-805S.5	Ø 2.3 Selftapping Screw - L 5 mm - Pentagon - 5 Pack	05407007751877
70-807S	Ø 2.3 Selftapping Screw - L 7 mm - Pentagon	05407007751891
70-807S.5	Ø 2.3 Selftapping Screw - L 7 mm - Pentagon - 5 Pack	05407007751914
70-809S	Ø 2.3 Selftapping Screw - L 9 mm - Pentagon	05407007751938
70-809S.5	Ø 2.3 Selftapping Screw - L 9 mm - Pentagon - 5 Pack	05407007751952
70-811S	Ø 2.3 Selftapping Screw - L 11 mm - Pentagon	05407007751976
70-811S.5	Ø 2.3 Selftapping Screw - L 11 mm - Pentagon - 5 Pack	05407007751990
70-813S	Ø 2.3 Selftapping Screw - L 13 mm - Pentagon	05407007752010
70-813S.5	Ø 2.3 Selftapping Screw - L 13 mm - Pentagon - 5 Pack	05407007752034
70-815S	Ø 2.3 Selftapping Screw - L 15 mm - Pentagon	05407007752058
70-815S.5	Ø 2.3 Selftapping Screw - L 15 mm - Pentagon - 5 Pack	05407007752072
70-817S	Ø 2.3 Selftapping Screw - L 17 mm - Pentagon	05407007752096
70-817S.5	Ø 2.3 Selftapping Screw - L 17 mm - Pentagon - 5 Pack	05407007752119
70-819S	Ø 2.3 Selftapping Screw - L 19 mm - Pentagon	05407007752133

Product code	Description	BASIC UDI-DI (GTIN)
70-819S.5	Ø 2.3 Selftapping Screw - L 19 mm - Pentagon - 5 Pack	05407007752157
70-905S	Ø 2.5 Selftapping rescue Screw - L 5 mm - Pentagon	05407007752171
70-905S.5	Ø 2.5 Selftapping rescue Screw - L 5 mm - Pentagon - 5 Pack	05407007752195
70-907S	Ø 2.5 Selftapping rescue Screw - L 7 mm - Pentagon	05407007752218
70-907S.5	Ø 2.5 Selftapping rescue Screw - L 7 mm - Pentagon - 5 Pack	05407007752232
71-205S	Ø 1.2 Selftapping Micro Screw - L 5 mm - Pentagon	05407007752256
71-205S.5	Ø 1.2 Selftapping Micro Screw - L 5 mm - Pentagon - 5 Pack	05407007752270
71-207S	Ø 1.2 Selftapping Micro Screw - L 7 mm - Pentagon	05407007752331
71-207S.5	Ø 1.2 Selftapping Micro Screw - L 7 mm - Pentagon - 5 Pack	05407007752355
71-209S	Ø 1.2 Selftapping Micro Screw - L 9 mm - Pentagon	05407007752416
71-209S.5	Ø 1.2 Selftapping Micro Screw - L 9 mm - Pentagon - 5 Pack	05407007752430
71-211S	Ø 1.2 Selftapping Micro Screw - L 11 mm - Pentagon	05407007752492
71-211S.5	Ø 1.2 Selftapping Micro Screw - L 11 mm - Pentagon - 5 Pack	05407007752515
71-213S	Ø 1.2 Selftapping Micro Screw - L 13 mm - Pentagon	05407007752577
71-213S.5	Ø 1.2 Selftapping Micro Screw - L 13 mm - Pentagon - 5 Pack	05407007752591
71-215S	Ø 1.2 Selftapping Micro Screw - L 15 mm - Pentagon	05407007752652
71-215S.5	Ø 1.2 Selftapping Micro Screw - L 15 mm - Pentagon - 5 Pack	05407007752676
71-217S	Ø 1.2 Selftapping Micro Screw - L 17 mm - Pentagon	05407007752737
71-217S.5	Ø 1.2 Selftapping Micro Screw - L 17 mm - Pentagon - 5 Pack	05407007752751
71-305S	Ø 1.4 Selfdrilling Micro-suspension Screw - L 5 mm - Pentagon	05407007752775
71-307S	Ø 1.4 Selfdrilling Micro-suspension Screw - L 7 mm - Pentagon	05407007752799
73-305S	Ø 1.8 Selftapping screw - L 5 mm - Round	05407007752812
73-305S.5	Ø 1.8 Selftapping screw - L 5 mm - Round - 5 Pack	05407007752836
73-307S	Ø 1.8 Selftapping screw - L 7 mm - Round	05407007752850
73-307S.5	Ø 1.8 Selftapping screw - L 7 mm - Round - 5 Pack	05407007752874