



DECLARATION OF CONFORMITY

MANUFACTURER NAME : ZIMED MEDİKAL SANAYİ VE TİCARET LIMITED ŞİRKETİ

ADRESS : Aydınlar Mah. 03070 Cad. No:4 Şehitkâmil 27580 Gaziantep-Türkiye

DEVICE NAME : Bone Screws

ROW NO	PRODUCT NO	PRODUCT NAME	RAW MATE RIAL	REF NO	GMDN	STERILIZATION
1.	8680941239145	CANNULATED SCREW 16 mm YİV. 7.3 X 40 mm (Ti)	ISO 5832-1	2042-0040	56642	NON-STERILE
2.	8680941232276	CANNULATED SCREW 16 mm YİV. 7.3 X 45 mm (Ti)	ISO 5832-1	2042-0045	56642	NON-STERILE
3.	8699131608470	CANNULATED SCREW 16 mm YİV. 7.3 X 50 mm (Ti)	ISO 5832-1	2042-0050	56642	NON-STERILE
4.	8699131608487	CANNULATED SCREW 16 mm YİV. 7.3 X 55 mm (Ti)	ISO 5832-1	2042-0055	56642	NON-STERILE
5.	8699131608494	CANNULATED SCREW 16 mm YİV. 7.3 X 60 mm (Ti)	ISO 5832-1	2042-0060	56642	NON-STERILE
6.	8699131608500	CANNULATED SCREW 16 mm YİV. 7.3 X 65 mm (Ti)	ISO 5832-1	2042-0065	56642	NON-STERILE
7.	8699131608517	CANNULATED SCREW 16 mm YİV. 7.3 X 70 mm (Ti)	ISO 5832-1	2042-0070	56642	NON-STERILE
8.	8699131608524	CANNULATED SCREW 16 mm YİV. 7.3 X 75 mm (Ti)	ISO 5832-1	2042-0075	56642	NON-STERILE
9.	8699131608531	CANNULATED SCREW 16 mm YİV. 7.3 X 80 mm (Ti)	ISO 5832-1	2042-0080	56642	NON-STERILE
10.	8699131608548	CANNULATED SCREW 16 mm YİV. 7.3 X 85 mm (Ti)	ISO 5832-1	2042-0085	56642	NON-STERILE
11.	8699131608555	CANNULATED SCREW 16 mm YİV. 7.3 X 90 mm (Ti)	ISO 5832-1	2042-0090	56642	NON-STERILE
12.	8699131608562	CANNULATED SCREW 16 mm YİV. 7.3 X 95 mm (Ti)	ISO 5832-1	2042-0095	56642	NON-STERILE
13.	8699131608579	CANNULATED SCREW 16 mm YİV. 7.3 X 100 mm (Ti)	ISO 5832-1	2042-0100	56642	NON-STERILE
14.	8699131608586	CANNULATED SCREW 16 mm YİV. 7.3 X 105 mm (Ti)	ISO 5832-1	2042-0105	56642	NON-STERILE
15.	8699131608593	CANNULATED SCREW 16 mm YİV. 7.3 X 110 mm (Ti)	ISO 5832-1	2042-0110	56642	NON-STERILE
16.	8699131647912	CANNULATED SCREW 16 mm YİV. 7.3 X 115 mm (Ti)	ISO 5832-1	2042-0115	56642	NON-STERILE
17.	8699131647929	CANNULATED SCREW 16 mm YİV. 7.3 X 120 mm (Ti)	ISO 5832-1	2042-0120	56642	NON-STERILE
18.	8699131649244	CANNULATED HERBERT SCREW 3.0 X 10 mm (Ti)	ISO 5832-1	2172-0010	56642	NON-STERILE
19.	8699131656075	CANNULATED HERBERT SCREW 3.0 X 12 mm (Ti)	ISO 5832-1	2172-0012	56642	NON-STERILE
20.	8699131649008	CANNULATED HERBERT SCREW 3.0 X 14 mm (Ti)	ISO 5832-1	2172-0014	56642	NON-STERILE

ROW NO	PRODUCT NO	PRODUCT NAME	RAW MATE RIAL	REF NO	GMDN	STERILIZATION
21.	8699131656099	CANNULATED HERBERT SCREW 3.0 X 16 mm (Ti)	ISO 5832-1	2172-0016	56642	NON-STERILE
22.	8699131649022	CANNULATED HERBERT SCREW 3.0 X 18 mm (Ti)	ISO 5832-1	2172-0018	56642	NON-STERILE
23.	8699131656112	CANNULATED HERBERT SCREW 3.0 X 20 mm (Ti)	ISO 5832-1	2172-0020	56642	NON-STERILE
24.	8699131649046	CANNULATED HERBERT SCREW 3.0 X 22 mm (Ti)	ISO 5832-1	2172-0022	56642	NON-STERILE
25.	8699131656136	CANNULATED HERBERT SCREW 3.0 X 24 mm (Ti)	ISO 5832-1	2172-0024	56642	NON-STERILE
26.	8699131649060	CANNULATED HERBERT SCREW 3.0 X 26 mm (Ti)	ISO 5832-1	2172-0026	56642	NON-STERILE
27.	8699131656150	CANNULATED HERBERT SCREW 3.0 X 28 mm (Ti)	ISO 5832-1	2172-0028	56642	NON-STERILE
28.	8699131656167	CANNULATED HERBERT SCREW 3.0 X 30 mm (Ti)	ISO 5832-1	2172-0030	56642	NON-STERILE
29.	8680941239145	CANNULATED SCREW 32 mm YİV. 7.3 X 40 mm (Ti)	ISO 5832-1	2252-0040	56642	NON-STERILE
30.	8680941232276	CANNULATED SCREW 32 mm YİV. 7.3 X 45 mm (Ti)	ISO 5832-1	2252-0045	56642	NON-STERILE
31.	9986131608470	CANNULATED SCREW 32 mm YİV. 7.3 X 50 mm (Ti)	ISO 5832-1	2252-0050	56642	NON-STERILE
32.	9986131608487	CANNULATED SCREW 32 mm YİV. 7.3 X 55 mm (Ti)	ISO 5832-1	2252-0055	56642	NON-STERILE
33.	9986131608494	CANNULATED SCREW 32 mm YİV. 7.3 X 60 mm (Ti)	ISO 5832-1	2252-0060	56642	NON-STERILE
34.	9986131608500	CANNULATED SCREW 32 mm YİV. 7.3 X 65 mm (Ti)	ISO 5832-1	2252-0065	56642	NON-STERILE
35.	9986131608517	CANNULATED SCREW 32 mm YİV. 7.3 X 70 mm (Ti)	ISO 5832-1	2252-0070	56642	NON-STERILE
36.	9986131608524	CANNULATED SCREW 32 mm YİV. 7.3 X 75 mm (Ti)	ISO 5832-1	2252-0075	56642	NON-STERILE
37.	9986131608531	CANNULATED SCREW 32 mm YİV. 7.3 X 80 mm (Ti)	ISO 5832-1	2252-0080	56642	NON-STERILE
38.	9986131608548	CANNULATED SCREW 32 mm YİV. 7.3 X 85 mm (Ti)	ISO 5832-1	2252-0085	56642	NON-STERILE
39.	9986131608555	CANNULATED SCREW 32 mm YİV. 7.3 X 90 mm (Ti)	ISO 5832-1	2252-0090	56642	NON-STERILE
40.	9986131608562	CANNULATED SCREW 32 mm YİV. 7.3 X 95 mm (Ti)	ISO 5832-1	2252-0095	56642	NON-STERILE
41.	9986131608579	CANNULATED SCREW 32 mm YİV. 7.3 X 100 mm (Ti)	ISO 5832-1	2252-0100	56642	NON-STERILE
42.	9986131608586	CANNULATED SCREW 32 mm YİV. 7.3 X 105 mm (Ti)	ISO 5832-1	2252-0105	56642	NON-STERILE
43.	9986131608593	CANNULATED SCREW 32 mm YİV. 7.3 X 110 mm (Ti)	ISO 5832-1	2252-0110	56642	NON-STERILE
44.	9986131647912	CANNULATED SCREW 32 mm YİV. 7.3 X 115 mm (Ti)	ISO 5832-1	2252-0115	56642	NON-STERILE
45.	9986131647929	CANNULATED SCREW 32 mm YİV. 7.3 X 120 mm (Ti)	ISO 5832-1	2252-0120	56642	NON-STERILE
46.	8699131643693	MALLEOLAR SCREW 4.5 X 25 mm (Ti)	ISO 5832-1	2092-0025	56642	NON-STERILE
47.	8699131643709	MALLEOLAR SCREW 4.5 X 30 mm (Ti)	ISO 5832-1	2092-0030	56642	NON-STERILE
48.	8699131643716	MALLEOLAR SCREW 4.5 X 35 mm (Ti)	ISO 5832-1	2092-0035	56642	NON-STERILE
49.	8699131643723	MALLEOLAR SCREW 4.5 X 40 mm (Ti)	ISO 5832-1	2092-0040	56642	NON-STERILE
50.	8699131643730	MALLEOLAR SCREW 4.5 X 45 mm (Ti)	ISO 5832-1	2092-0045	56642	NON-STERILE
51.	8699131643747	MALLEOLAR SCREW 4.5 X 50 mm (Ti)	ISO 5832-1	2092-0050	56642	NON-STERILE
52.	8699131643754	MALLEOLAR SCREW 4.5 X 55 mm (Ti)	ISO 5832-1	2092-0055	56642	NON-STERILE
53.	8699131643761	MALLEOLAR SCREW 4.5 X 60 mm (Ti)	ISO 5832-1	2092-0060	56642	NON-STERILE
54.	8699131643778	MALLEOLAR SCREW 4.5 X 65 mm (Ti)	ISO 5832-1	2092-0065	56642	NON-STERILE
55.	8699131643785	MALLEOLAR SCREW 4.5 X 70 mm (Ti)	ISO 5832-1	2092-0070	56642	NON-STERILE
56.	8699131643792	MALLEOLAR SCREW 4.5 X 75 mm (Ti)	ISO 5832-1	2092-0075	56642	NON-STERILE
57.	8699131643808	MALLEOLAR SCREW 4.5 X 80 mm (Ti)	ISO 5832-1	2092-0080	56642	NON-STERILE
58.	8699131643815	MALLEOLAR SCREW 4.5 X 85 mm (Ti)	ISO 5832-1	2092-0085	56642	NON-STERILE

PRODUCT CLASS : **CLASS IIb (According to Annex 9 Rule 8)**

GMDN CODE : **56642**

CONF. ASSESSMENT ROUTE : **ANNEX-II.3**

We here by declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC by annex directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED : EN ISO 13485:2016, TS EN ISO 9001:2015, EN ISO 14971:2012, EN ISO 14602:2010, EN ISO 5832-3:2016, TS EN 62366-1:2015, EN ISO 11737-1 : 2006, EN ISO 14630:2010, TS EN ISO 17664:2018, TS EN ISO 17665-1, ISO 5832-3:2016, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2005, TS EN ISO 11607-1 :2017, TS EN ISO 11607-2 :2017, EN ISO 11137-1:2015 ,EN ISO 11137-2:2015, EN ISO 11135:2014, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 14971 :2012, EN ISO 10993-1:2009, EN ISO 15223-1:2016, EN 1041:2008, MEDDEV 2.7.1 REV4

NOTIFIED BODY : **KIWA BELGELENDİRME HİZMETLERİ A.Ş, ITOSB 9. Cad. No:15 Tepeören Tuzla İstanbul Türkiye , NB1984.**

EC CERTIFICATE NUMBER : **1984-MDD-11-129**

START OF CE MARKING DATE : **11.11.2011**

PLACE, DATE OF ISSUE : **17.04.2020, GAZİANTEP**

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