



DECLARATION OF CONFORMITY

MANUFACTURER NAME : ZİMED MEDİKAL SANAYİ VE TİCARET LİMİTED

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

DEVICE NAME : DHS-DCS Bone Plates

NO	PRODUCT NO	PRODUCT NAME	RAW MATERIAL	REF NO	GMDN	STERILIZATION
1.	8699131601174	DHS PLATE 2 H	ISO 5832-1	166.022	46647	NON-STERILE
2.	8699131601181	DHS PLATE 3 H	ISO 5832-1	166.023	46647	NON-STERILE
3.	8699131601198	DHS PLATE 4 H	ISO 5832-1	166.024	46647	NON-STERILE
4.	8699131601204	DHS PLATE 5 H	ISO 5832-1	166.025	46647	NON-STERILE
5.	8699131601211	DHS PLATE 6 H	ISO 5832-1	166.026	46647	NON-STERILE
6.	8699131601228	DHS PLATE 7 H	ISO 5832-1	166.027	46647	NON-STERILE
7.	8699131601235	DHS PLATE 8 H	ISO 5832-1	166.028	46647	NON-STERILE
8.	8699131601242	DHS PLATE 9 H	ISO 5832-1	166.029	46647	NON-STERILE
9.	8699131601259	DHS PLATE 10 H	ISO 5832-1	166.030	46647	NON-STERILE
10.	8699131601280	DCS PLATE DCP HOLE 95 , 6H	ISO 5832-1	167.006	46647	NON-STERILE
11.	8699131601297	DCS PLATE DCP HOLE 95 , 7H	ISO 5832-1	167.007	46647	NON-STERILE
12.	8699131601303	DCS PLATE DCP HOLE 95 , 8H	ISO 5832-1	167.008	46647	NON-STERILE
13.	8699131601310	DCS PLATE DCP HOLE 95 , 9H	ISO 5832-1	167.009	46647	NON-STERILE
14.	8680941237431	DCS PLATE DCP HOLE 95 , 10H	ISO 5832-1	167.010	46647	NON-STERILE
15.	8699131631270	DCS PLATE DCP HOLE 95 , 12H	ISO 5832-1	167.012	46647	NON-STERILE
16.	8699131631287	DCS PLATE DCP HOLE 95 , 14H	ISO 5832-1	167.014	46647	NON-STERILE
17.	8699131631294	DHS/DCS Screw with Compression Screw 50 mm	ISO 5832-1	168.050	56642	NON-STERILE
18.	8699131631300	DHS/DCS Screw with Compression Screw 55 mm	ISO 5832-1	168.055	56642	NON-STERILE
19.	8699131631317	DHS/DCS Screw with Compression Screw 60 mm	ISO 5832-1	168.060	56642	NON-STERILE
20.	8699131631324	DHS/DCS Screw with Compression Screw 65 mm	ISO 5832-1	168.065	56642	NON-STERILE
21.	8699131631331	DHS/DCS Screw with Compression Screw 70 mm	ISO 5832-1	168.070	56642	NON-STERILE

22.	8699131631348	DHS/DCS Screw with Compression Screw 75 mm	ISO 5832-1	168.075	56642	NON-STERILE
23.	8699131631355	DHS/DCS Screw with Compression Screw 80 mm	ISO 5832-1	168.080	56642	NON-STERILE
24.	8699131631362	DHS/DCS Screw with Compression Screw 85 mm	ISO 5832-1	168.085	56642	NON-STERILE
25.	8699131631386	DHS/DCS Screw with Compression Screw 90 mm	ISO 5832-1	168.090	56642	NON-STERILE
26.	8699131631393	DHS/DCS Screw with Compression Screw 95 mm	ISO 5832-1	168.095	56642	NON-STERILE
27.	8699131631409	DHS/DCS Screw with Compression Screw 100 mm	ISO 5832-1	168.100	56642	NON-STERILE
28.	8699131631553	DHS/DCS Screw with Compression Screw 105 mm	ISO 5832-1	168.105	56642	NON-STERILE
29.	8699131631560	DHS/DCS Screw with Compression Screw 110 mm	ISO 5832-1	168.110	56642	NON-STERILE
30.	8699131631577	DHS/DCS Screw with Compression Screw 115 mm	ISO 5832-1	168.115	56642	NON-STERILE
31.	8699131631584	DHS/DCS Screw with Compression Screw 120 mm	ISO 5832-1	168.120	56642	NON-STERILE

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

GMDN CODE : **56642, 46647**

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 62366:2015, EN ISO 11737-1 : 2006, EN ISO 14630:2010, EN, EN ISO 10993-1:2009, ISO 5832-3:2016, ASTM F136, ISO 5832-2:2018, ASTM F67, EN ISO 15223-1:2016, EN 1041:2008, MEDDEV 2.7.1 REV4

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

EC CERTIFICATE NUMBER : 1984-MDD-11-129

START OF CE MARKING DATE : 11 KASIM 2011

PLACE, DATE OF ISSUE : 05.11.2019, GAZIANTEP



SERHAT DIRGAR

GENERAL MANAGER

17.04.2020

GAZIANTEP / TURKEY