



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 : External Fixator System and SKELETAL Pins

ROW NO	PRODUCT NO	PRODUCT NAME	ROW MATERIAL	REF NO	GMDN CODE	STERILIZATION
1.	8699131616734	SINGLE PIN CLAMP Ø11 mm Rod	304 SS	210.001	48011	NON-STERILE
2.	8699131616741	SINGLE PIN CLAMP Ø8 mm ROD	304 SS	210.001	48011	NON-STERILE
3.	8699131616758	CLIP ON SELF HOLDING CLAMP Ø8 mm	304 SS	210.011	48011	NON-STERILE
4.	8699131616765	TUBULER FIXATOR ROD Ø 11 x 100 mm	304 SS	210.050	48011	NON-STERILE
5.	8699131616772	TUBULER FIXATOR ROD Ø 11 x 150 mm	304 SS	210.051	48011	NON-STERILE
6.	8699131616789	TUBULER FIXATOR ROD Ø 11 x 200 mm	304 SS	210.052	48011	NON-STERILE
7.	8699131616796	TUBULER FIXATOR ROD Ø 11 x 250 mm	304 SS	210.053	48011	GAMA
8.	8699131616802	TUBULER FIXATOR ROD Ø 11 x 300 mm	304 SS	210.054	48011	GAMA
9.	8699131616819	TUBULER FIXATOR ROD Ø 11 x 350 mm	304 SS	210.055	48011	GAMA
10.	8699131616826	TUBULER FIXATOR ROD Ø 11 x 400 mm	304 SS	210.056	48011	NON-STERILE
11.	8699131616833	TUBULER FIXATOR ROD Ø 11 x 450 mm	304 SS	210.057	48011	NON-STERILE
12.	8699131616840	TUBULER FIXATOR ROD Ø 11 x 500 mm	304 SS	210.058	48011	NON-STERILE
13.	8699131616857	TUBULER FIXATOR ROD Ø 8 x 100 mm	304 SS	310.058	48011	NON-STERILE
14.	8699131616864	TUBULER FIXATOR ROD Ø 8 x 150 mm	304 SS	310.058	48011	NON-STERILE
15.	8699131616871	TUBULER FIXATOR ROD Ø 8 x 200 mm	304 SS	310.058	48011	NON-STERILE
16.	8699131616888	TUBULER FIXATOR ROD Ø 8 x 250 mm	304 SS	310.058	48011	NON-STERILE
17.	8699131616895	TUBULER FIXATOR ROD Ø 8 x 300 mm	304 SS	310.058	48011	NON-STERILE
18.	8699131616901	TUBULER FIXATOR ROD Ø 8 x 350 mm	304 SS	310.058	48011	NON-STERILE
19.	8699131616918	TUBULER FIXATOR ROD Ø 8 x 400 mm	304 SS	310.058	48011	NON-STERILE
20.	8699131616925	TUBULER FIXATOR ROD Ø 8 x 450 mm	304 SS	310.058	48011	NON-STERILE
21.	8699131616932	TUBULER FIXATOR ROD Ø 8 x 500 mm	304 SS	310.058	48011	NON-STERILE
22.	8699131685495	SCHANZ SCREW CORTICAL THREAD 3X100 mm (SS)	ISO 5832-1	211.3100	48011	NON-STERILE
23.	8699131685501	SCHANZ SCREW CORTICAL THREAD 4X100 mm (SS)	ISO 5832-1	211.4100	48011	NON-STERILE
24.	8699131685518	SCHANZ SCREW CORTICAL THREAD 5X100 mm (SS)	ISO 5832-1	211.5100	48011	NON-STERILE
25.	8699131616819	KIRSCHNER WIRE 1.0 x 300 mm	ISO 5832-1	6041-1030	48011	NON-STERILE
26.	8699131616826	KIRSCHNER WIRE 1.5 x 300 mm	ISO 5832-1	6041-1530	48011	NON-STERILE

ROW NO	PRODUCT NO	PRODUCT NAME	ROW MATERIAL	REF NO	GMDN CODE	STERILIZATION
27.	8699131616833	KIRSCHNER WIRE 2.0 x 300 mm	ISO 5832-1	6041-2030	48011	NON-STERILE
28.	8699131616840	THREADED KIRSCHNER WIRE 2.0 x 300 mm	ISO 5832-1	6031-2030	48011	NON-STERILE
29.	8699131616857	THREADED KIRSCHNER WIRE 2.5 x 300 mm	ISO 5832-1	6031-2530	48011	NON-STERILE

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

GMDN CODE : **48011, 48012, 32854,35685**

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, EN ISO 9001:2015, ISO 14630:2012, ASTM F 1541 – 02: 2015, ISO 14602:2010, EN ISO 5832-1:2016, ISO 5832-3:2016, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2005, ISO 17664:2017, TS EN ISO 11607-1 :2017, TS EN ISO 11607-2 :2017, ISO 14698-1: 2003, 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 556-1:2001/AC:2006, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971 :2012, 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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