

DECLARATION OF CONFORMITY

MANUFACTURER :MATEK MEDİKAL AYGITLAR TEKNOLOJİ
SAN. VE TİC. A.Ş.

ADDRESS : ANADOLU O.S.B. MAH. 29 EKİM CAD. NO. 39 MALİKÖY-
SİNCAN /ANKARA -TÜRKİYE

PRODUCT : ELIITESHARP Injection Needle, Sterile

GMDN :45019

PRODUCT NAME	CODE NO	DIAMETER (G)	LENGHT (CM)
Injection Needle, Metal	MIN1835M	18	35
Injection Needle, Metal	MIN1935M	19	35
Injection Needle, Metal	MIN2035M	20	35
Injection Needle, Metal, Plastic Hub	MIN1835	18	35
Injection Needle, Metal, Plastic Hub	MIN1935	19	35
Injection Needle, Metal, Plastic Hub	MIN2035	20	35
Injection Needle, Plastic	MIN1835P	18	35
Injection Needle, Plastic	MIN1935P	19	35
Injection Needle, Plastic	MIN2035P	20	35

CLASSIFICATION : CLASS IIa , ANNEX-IX, RULE 6

**CONFORMITY
ASSESSMENT
ROUTE** : ANNEX V

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AND 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

APPLICABLE STANDARTS :EN ISO 13485:2012, EN ISO 13485:2016, EN ISO 9001:2008, EN ISO 9001:2015, EN ISO 14971:2013, EN ISO 11737-1:2018, EN ISO 11737-2:2010, EN 868-2:2017, EN 868-3:2017, EN ISO 19011:2012, EN ISO 11135:2014, EN ISO 10993-1:2011, EN ISO 10993-5:2010, EN ISO 10993-10:2014, EN ISO 15223-1:2016, TS EN ISO 9626:2016, EN ISO 14644-1:2016, EN ISO 14644-2:2016, EN ISO 14644-3:2006, EN ISO 1041+A1:2014, EN ISO 11607-1:2017, EN ISO 14644-8:2013, EN ISO 17050-1:2010, EN ISO 17050-2:2005, ASTM B 192, ASTM D 5276, ASTM F 1929, ASTM F 1980, MDD 93/42 EEC, MEDDEV 2.7.1 Rev 4:2016, MEDDEV 2.12-1 rev8:2013, MEDDEV 2.12-2 rev2: 2012, MEDDEV 2.4/1:rev9:2010, MEDDEV 2.5/5: Rev3:1998,

NAME OF NOTIFIED BODY : KIWA CERTIFICATION SERVICES INC. (1984)
Kiwa Belgelendirme Hizmetleri A.Ş
İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul TÜRKİYE
Tel: +90 216 593 25 75

CERTIFICATE NUMBER : 1984-MDD-19-567

PLACE, DATE OF ISSUE : ANKARA, 31.01.2019

SIGNATURE : LEVENT HAYYAOĞLU
GENERAL MANAGER

Matek
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GM.DEC-02 Rev.05 Rev. Date:31.01.2019