



EC DECLARATION

Document number	Revision date	Revision number	Revision date
TD.01.51	14.05.2018	04	15/03/2022



EC DECLARATION OF CONFORMITY

Tıbbi Cihaz Yönetmeliği (93/42/AT)- Medical Devices Directive 93/42/EEC

COMPANY NAME : ŞAFAK MEDİKAL TIBBİ MALZEMELER İTHALAT İHRACAT

AUTHORIZED PERSON/TITLE : Kenan DAŞDEMİR /Sorumlu Müdür

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As, our products, whose models and GMDN Codes are specified in TD.01.22 Product List Rev.01;



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EN ISO 13485:2016	EN 15223-1:2016	EN 1041:2008+A1:2013
EN ISO 14971:2012	EN ISO 10993-1: 2009/AC:2010	EN ISO 10993-5: 2009
EN ISO 11135:2014	EN ISO 11737-1:2018	EN ISO 11737-2:2009
EN ISO 11607-1:2017	EN ISO 11607-2:2017	EN 62366-1:2015
EN 868-5:2009	EN ISO 7886-1:2018	EN ISO 10993-11:2009
EN ISO 10993-10:2013	EN ISO 10993-4:2017	EN ISO 80369-7:2017
EN ISO 80369-20:2015	EN ISO 14644-1:2015	EN ISO 14644-2:2015
EN ISO 14644-3:2005	EN ISO 14644-4 :2001	EN ISO 14644-5:2004
EN ISO 14698-1:2003	EN ISO 14698-2/AC:2006	ASTM F88/F88-M:2015
ASTM F1980:2016	EN ISO 6009:2016	

Manufactured to harmonized standards , And

Medical Device Directive 93/42/EC Annex V
Production Quality Assurance
Hypodermic Sterile Syringe, Hypodermic Needle and
Multi-Packed Needle Hypodermic Syringe
Class IIa
(Annex IX of 93/42/EC, Rule 6)

We declare that it complies with its terms.

Authorized Institution : UDEM International Certification Audit Training Center
Notified Body Identity Number : 2292
Certificate No : M.2019.106.11994
Initial Assessment Date : 05.04.2019
Registration Date : 20.05.2019
Revision Date/No : 18.05.2021/01
Expiry Date : 19.05.2024
Place of Declaration : BOLU
Declaring : Bayram Daşdemir /PRODUCTON MANAGER
Approval : KENAN DAŞDEMİR

ŞAFAK MEDİKAL
TIBBİ CİHAZLAR SARF MALZEMELER
Kenan DAŞDEMİR
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PRODUCT	GMDN CODE
Hypodermic syringe sterile with needle 1 m	47017
Hypodermic syringe sterile with needle 10 ml	47017
Hypodermic syringe sterile with needle 10 ml	47017
Hypodermic syringe sterile with needle 20 ml	47017
Hypodermic syringe sterile with needle 20 ml	47017
Hypodermic syringe sterile with needle 2 ml	47017
Hypodermic syringe sterile with needle 2 ml	47017
Hypodermic syringe sterile with needle 5 ml	47017
Hypodermic syringe sterile with needle 5 ml	47017

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