AB UYGUNLUK BEYANI
EC DECLARATION OF CONFORMITY

ÜRETİCİ FİRMA ADI: *COMPANY NAME:*	Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret A.Ş.
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E-MAIL:	info@turkuazsaglik.com.tr
ÜRÜN ADI: *PRODUCTS:*	Steril Ultrason Jeli Sterile Ultrasound Gel
MARKA: *TRADE MARK:*	Konix
Modeller ve Referans No.: *MODEL(S)and Ref No.:*	20 ml | T0000.102.0001
GMDN KODU: *GMDN CODE:*	58735
SINIFLANDIRMA: *CLASSIFICATION:*	Annex IX of MDD 93/42/EEC Class IIa, Rule 5
UYGUNLUK DEĞERLENDİRME YOLU: *CONFORMITY ASSESSMENT ROUTE:*	MDD 93/42/EEC ANNEX II (section 4 excluded) (Bölüm 4 Hariç)
UYGULANABİLİR STANDARTLAR: *APPLICABLE STANDARDS:*	EK I'e bakınız: TD-05/2.5 See Appendix I: TD-05/2.5
VERİLİŞ TARİHİ: *ISSUE DATE:*	9.03.18

YUKARIDA ADI GEÇEN ÜRÜNLERİN 2007/47/EC EKLENTİSİ DAHİL 93/42/EEC TIBBİ CİHAZLAR YÖNETMELİĞİ GEREKSİNİMLERİNİ KARŞILADIĞINI BEYAN EDERİZ. İLGİLİ DESTEKLEYİCİ TÜM DOKÜMANLAR ÜRETİCİ TESİSİNDE BULUNMAKTADIR.
WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC INCLUDING 2007/47/EC AMENDMENT FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

ONAYLANMIŞ KURULUŞ ADI VE NUMARASI: *NOTIFIED BODY NAME & ID:*	UDEM - 2292
CE BELGESI SERTIFIKA NUMARASI : CE CERTIFICATE NUMBER :	M.2018.106.9377
CE BELGESI BİTİŞ TARİHİ : CE CERTIFICATE EXPIRATION DATE :	6.03.23

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN ve TİC. A.Ş
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İMZA: *SIGNATURE:*

Nurhan IRMAK
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DEPUTY GENERAL MANAGER

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93/42/EEC (2007/47/EEC)
Medical Device Directive

EN ISO 13485 : 2012
Quality Management Systems - Medical devices system requirements for regulatory purpose

EN ISO 14971:2012
Medical devices –Risk Management

EN 1041:2008+A:2013
Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2016
Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

EN ISO 11607-1:2017
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN ISO 11607-2:2017
Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

TS EN ISO 14644-1:2016
Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness

TS EN ISO 14644-2:2016
Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

TS EN ISO 14644-3:2006
Cleanrooms and associated controlled environments - Part 3: Test methods

EN ISO 11737-1:2006/AC:2009
Sterilization of medical devices-Microbiological methods – Part1:Determination of a population of microorganisms on products

EN ISO 11737-2:2009
Sterilization of medical devices- Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process

EN ISO 11137-1:2015
Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11137-1:2015/prA2
Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

Approval
Eda ÇELİK BİNİCİ
Kalite Güvence Uzmanı

Liste Güncelleme:12.12.2017

EN 1041:2008/A12013
Information supplied by the manufacturer of medical devices

EN ISO 10993-1:2009/AC:2010
Biological evaluation of medical devices – Part 1: Evaluation and testing

EN ISO 10993-5:2009
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

TS EN ISO 10993-10:2014
Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

EN ISO 14155:2011
Clinical investigation of medical devices for human subjects -- Good clinical practice

EN 62366-1:2015
Medical devices. Application of usability engineering to medical devices

ASTM-F 1980-16:2011
Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

MEDDEV 2.7/1 rev.4
Clinical evaluation: Guide for manufacturers and notified bodies

MEDDEV 2.12/1 rev.8
Medical devices vigilance system

MEDDEV 2.12/2 rev.2
Post Market Clinical Follow-up studies

European Pharmacopoeia
9th Edition

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Kalite Güvence Uzmanı