



DECLARATION OF CONFORMITY

MANUFACTURER : AĞAOĞLU TIBBİ SAĞLIK TEKSTİL SAN. VE TİC. A.Ş.
ADRES / ADDRESS : Organize Sanayi Bölgesi 104. Cad. No:219 UŞAK / TÜRKİYE
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PRODUCT : Non- Sterile XR/Non XR Gauze Compresses (Sponges)
None -Sterile XR/Non XR Gauze Compresses(Surgical Sponges,Lap Sponges)
None -Sterile XR/Non XR Cotton Pads

CLASSIFICATION : 93/42/EEC, ANNEX IX, RULE VI, CLASS IIa

CONFORMITY ASSESSMENT : MDD 93/42/EEC ANNEX V Production Quality Assurance System

CONFORMITY ASSESSMENT ROUTE:
WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY : Tatlısu Mahallesi Akif İnan Sokak no:1 34774 Ümraniye/İSTANBUL
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NOTIFIED BODY NUMBER : NB 2195

CERTIFICATE NO : 2195-MED-1224501

CERTIFICATE DATE OF ISSUE : 01.09.2012

CERTIFICATE VALID UNTIL : 26.05.2024

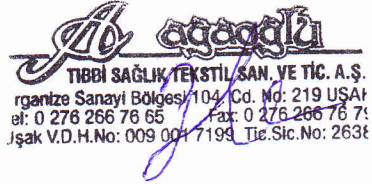
STANDARDS APPLIED : EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 10993-11:2017
EN ISO 10993-12:2012
EN ISO 9001:2015
EN 15223:2016
EN 1041+A1:2014
EN ISO 62366-1:2015

EN ISO 17665-1: 2006
EN ISO 17665-2: 2009
EN ISO 17665-3: 2013
EN ISO 11737-1: 2018
EN ISO 11737-2: 2019
TS EN 14079 :2007
TS 4786/T1: 2017

GMDN CODES

: 48133 – Non Sterile Gauze Compresses (Sponges) with/without XR
44971 - Non Sterile Gauze Compresses Lap Sponges (Surgical Sponges) Without XR
58802 - Non Sterile Gauze Compresses Lap Sponges (Surgical Sponges) Without XR
32572 -Non-Sterile Cotton Pads with /Without XR

GENERAL MANAGER
HALİL AĞAOĞLU
07.04.2022
UŞAK


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