

DECLARATION OF CONFORMITY

MANUFACTURER : GENCO TIBBI CIHAZLAR SAN. TIC. LTD. ŞTİ.

ADDRESS : 1571 SOK. NO: 22 KAT: 2 ÇINARLI /İZMİR/ TURKEY

PRODUCT : SPONJEL

SIZE : 80x50x10 mm, 70x50x10 mm, 80x50x1 mm, 200x70x0,5 mm,10x10x10 mm,
30x30x10 mm, 30x80 mm, 80x40x10 mm, 80x20x10 mm, 250x80x10 mm,
20x20x0,7 mm, 80x20x10 mm, 125x80x10 mm,80x15x0,7 mm,60x20x0,7 mm

DIRECTIVE : 93/42/EEC Medical devices directive incl. Amendment 2007/47/EC Annex IX

EN ISO 13485:2016, EN ISO 14971:2012, EN 556-1:2001, EN 556-2:2015, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN ISO 11737-1:2018, EN ISO 11737-2:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2005, EN ISO 14698-1:2003, EN 868-5:2009, ASTM F1980-16, ASTM F1929-15

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. INCL. AMENDMENT 2007/47/EC ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.WE DECLARE THAT OUR PRODUCTS DO NOT CONTAINS HUMAN BLOOD, ANIMAL LEATHER AND DERIVATE OF THESE GOODS.

PLACE, DATE OF ISSUE : İZMİR,

SIGNATURE : GENERAL MANAGER
ALİ OMUR