

## DECLARATION OF CONFORMITY

**MANUFACTURER** : GENCO TIBBI CIHAZLAR SAN. TIC. LTD. ŐTI.  
**ADDRESS** : 1571 SOK. NO: 22 KAT: 2 INARLI /IZMIR/ 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