

DECLARATION OF CONFORMITY

MANUFACTURER : GENCO TIBBI CIHAZLAR SAN. TIC. LTD. ŞTI.
ADDRESS : 1571 SOK. NO: 22 KAT: 2 ÇINARLI /IZMIR/ TURKEY
PRODUCT : UNOSPLINT
DESCRIPTION : EXTERNAL ALUMINIUM NASAL SPLINT, EXTERNAL THERMOPLASTIC NASAL SPLINT,
INTERNAL SILICON NASAL SPLINT WITH AIRWAY, PRECUT SILICON NASAL SPLINT
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