

# EC DECLARATION OF CONFORMITY

We, NÜVE Sanayi Malzemeleri İmalat ve Ticaret A.Ş.  
Saracalar Mah. Saracalar Kümeevleri No: 4/2  
Akyurt 06750 Ankara / TURKEY

herewith declare that the following described product meets the provisions of the Council Directive 93/42/EEC (2007/47/EC) for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

**PRODUCT:** STEAM STERILIZER

**MODEL:** NC 90M

**CLASSIFICATION:** IIB, Annex IX - RULE 15

**GMDN:** 35929

**CONFORMITY ASSESMENT ROUTE:** MDD 93/42/EEC (2007/47/EC), ANNEX II.3

**APPLICABLE HARMONISED STANDARDS:**

EN 61010-1: 2010      EN 62304: 2006  
EN 61326-1: 2013      EN 62366-1: 2015  
EN 61010-2-040: 2015      EN ISO 12100: 2010  
EN 60601-1-6: 2010

**NOTIFIED BODY:** KİWA BELGELENDİRME HİZMETLERİ  
A.Ş. (İTOSB) İstanbul Tuzla Organize Sanayi  
Bölgesi Tepeören Mevkii 34957 Tuzla-İstanbul  
TURKEY

**CERTIFICATE NUMBER:** 1984-MDD-10-030

**DATE OF ISSUE:** February 19, 2019

**SIGNATURE:**



Beril İZGİN  
General Manager

**CE**  
1984