

# EC DECLARATION OF CONFORMITY

We, NÜVE Sanayi Malzemeleri İmalat ve Ticaret A.Ş.  
Saracalar Mah. Saracalar Kümeevleri No: 4/2 (Eski Esenboğa Yolu 22 Km.)  
Akyurt 06750 Ankara / TURKEY

Hereby, we declare that the product named below complies with the standards listed in the following lines. As NÜVE Sanayi Malzemeleri İmalat ve Ticaret A.Ş., we declare that the device in question within the scope of this declaration complies with the 93/42/EEC Medical Device Directive and that the requirements specified in the directive for these devices have been met. All documents supporting this claim are kept by our company as the manufacturer.

**PRODUCT:** STEAM STERILIZER

**MODEL:** NC 40M / NC 90M

**CLASSIFICATION:** IIB, ANNEX IX – RULE 15

**GMDN:** 35929

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

**APPLICABLE HARMONISED STANDARDS :**

EN 61010-1: 2010/A1:2019      EN 62304: 2009  
EN 61326-1: 2021                EN 62366-1: 2015  
EN 61010-2-040: 2021        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/TÜRKİYE

**CERTIFICATE NUMBER:** 1984-MDD-10-030 Rev No: 10

**SIGNATURE:** Beril İZGİN  
General Manager

