

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 100
CLASSIFICATION: IIB, Annex IX - RULE 15
GMDN: 38671
CONFORMITY ASSESMENT ROUTE: MDD 93/42/EEC (2007/47/EC), ANNEX II.3

APPLICABLE HARMONISED STANDARDS:

EN 285: 2015 EN 62304: 2006
EN 61010-1: 2010 EN 62366-1: 2015
EN 61326-1: 2013 EN 60601-1-6: 2010
EN 61010-2-040: 2015 EN ISO 12100: 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 IZGIN
General Manager

CE
1984