EC DECLARATION OF CONFORMITY

Document No	Release date	Revision No	Revision Date
TD. ECD. 01	03.01.2019	00	-----

Digitally signed by Botnaru Andrei
Date: 2025.04.08 11:43:51 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CE

EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

Company Name	:	Tek-Bal Tıbbi Cihazlar San. Tic. Ltd. Şti.
Authorized Person/Title	:	Demet Yaşar / General Manager
Adress	:	Maltepe Mah. Dokumacılar Sitesi No:36 Zeytinburnu / İstanbul / Türkiye
Phone	:	+90 212 482 27 34
Fax	:	+90 212 482 33 86
Web/Mail	:	www.tek-bal.com / info@tek-bal.com

As, for our "Autoclave Sterilizer" device, whose GMDN Code is specified in Annex-1 GMDN Code Table with First Publication Date of 03.01.2019;

With Relevant Harmonized Standards		
EN ISO 13485: 2016	EN 62366-1:2015/A1:2020	EN ISO 15223-1:2021
EN ISO 20417:2021	EN 60601-1-6:2010/A2:2021	EN ISO 14971:2019
EN 60601-1:2006/AC:2022-12	EN 60601-1-2:2015/A1:2021	EN 60601-1-8:2007/A2:2021
EN 62304:2006/A1:2015	EN 285:2015+A1:2021	EN ISO 17665-1:2006
EN 13445-1: 2021	EN 13445-2:2021	EN 13445-3:2021
EN 13445-4: 2021	EN 13445-5:2021	EN 13445-6:2021
EN 61010-1: 2010/A1:2019/AC:2019-04	EN IEC 61010-2-040:2021	EN 13060:2014+A1:2018
Other Regulations, Legislation and Guidelines		
NBOG 2010-1: 2010	ISO 80002-2:2017	EN 12347:1998
Meddev 2.7/1 rev.4	ISO 31000:2018	2014/68/EU:2014
Meddev 2.12-1 rev.8	2006/95/AT:2006	
Meddev 2.12-2 rev.2	2004/108/AT:2004	

Manufactured to harmonized standards and

EC DECLARATION OF CONFORMITY

Document No	Release date	Revision No	Revision Date
TD. ECD. 01	03.01.2019	00	-----

Medical Device Directive 93/42/EC Annex II (Except Article 4)

Full Quality Assurance System

Class IIb

(Annex IX of 93/42/EC, Rule 15)

We declare that it complies with its terms.

Notified Body	:	SZUTEST Uygunluk Değerlendirme A.Ş.
Notified Body No	:	2195
Notified Body Adress	:	Tatlısu, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul
GMDN Code and Description	:	38671- Steam Sterilizer; A mains power (operated on AC power) designed for the complete elimination and/or inactivation of microorganisms from medical devices and related products using pressurized steam (ie moist heat) as the sterilizing agent; It is used for products that are not sensitive to high temperature, water or steam. Typically includes a racked processing room for device docking and controls; may be intended to sterilize wrapped and/or unwrapped devices. The device is available in a variety of shapes and sizes, including standalone (stack) and tabletop units.
Certificate No.	:	2195-MED-2012802
Certificate Issue Date	:	07.05.2020
Certificate Validity Date	:	26.05.2024
Declaration Date	:	03.01.2019
Place of Declaration	:	İstanbul
Declaring	:	Demet Yaşar
İmza	:	