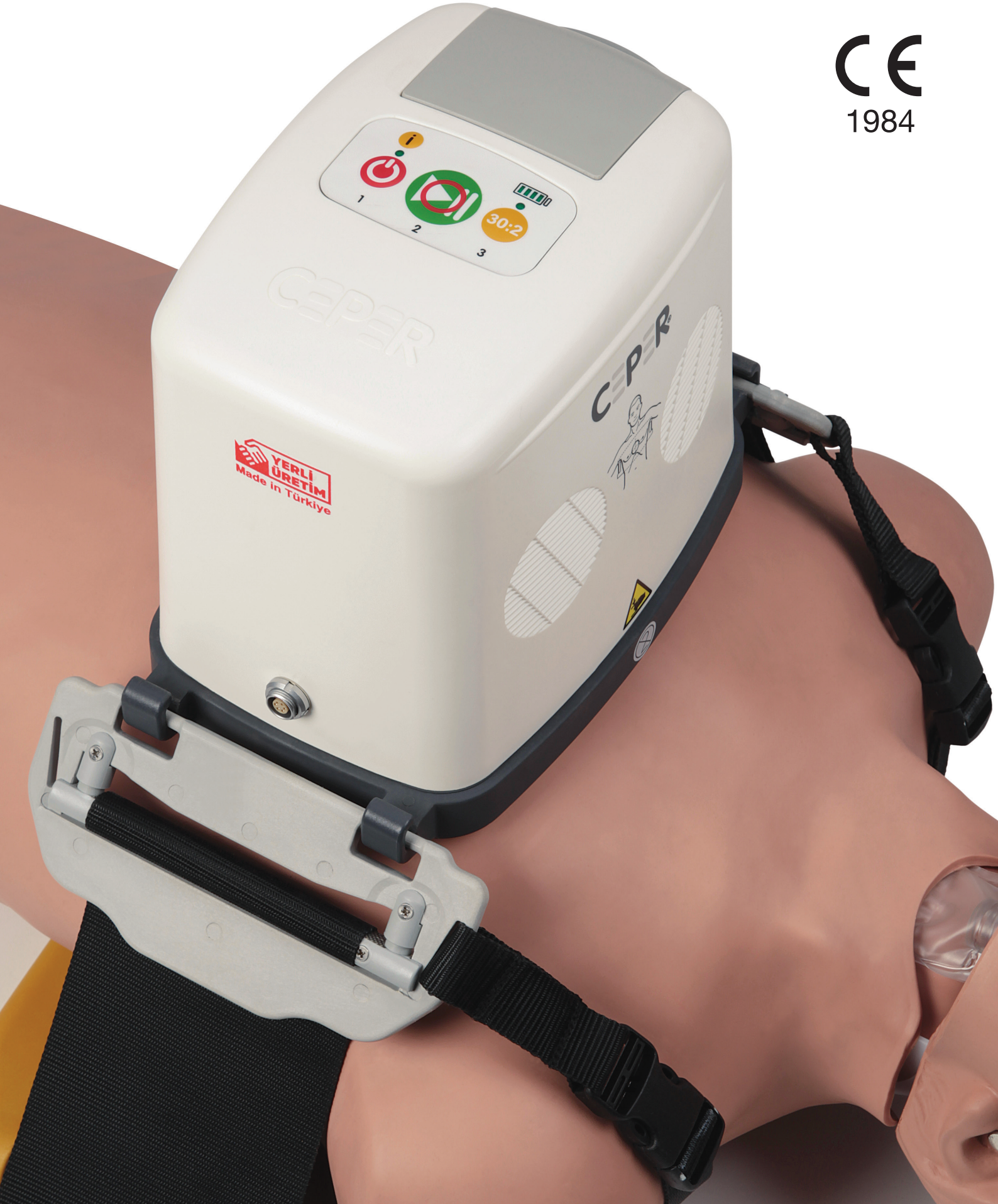
The first and only in Türkiye!

CEPER®1

AUTOMATIC CPR CHEST COMPRESSION DEVICE

CE
1984



My name is CEPER

My mission is to help saving lives!

- I perform high quality, safe and continuous chest compressions at the moments when emergency response teams require during cardiac arrest cases.
- I obtained my strength from my knowledge and technical experience of 55 years.
- My priority is to be the best functional design, quality and production.
- I am fast and easy to install and I am reliable.

1 I'm consistent...

With a fully charged battery, I perform 110 compressions per minute at a depth of 52mm continuously for 60 minutes.

2 I'm efficient...

I don't require extra personnel for continuous compression. I allow more time for emergency teams to focus on other patients and I contribute to increasing staff productivity.

3 I operate in all environments and conditions...

I perform chest compressions continuously and consistently until the emergency response is finished at home, on the street, on the mountain, in the park, in the office, on the road, on the stretcher, in the ambulance, in the car, in the helicopter, in the hospital, on the ship.

4 I am simple and clear...

With the intervention of two personnel from the emergency team, I can be immobilized to the patient and become ready for use in 10-15 seconds. My clear and simple control panel activates my functions in a few steps.

5 I'm not affected by the virus...

I minimize virus interaction between the emergency teams and the patient.

6 I'm safe...

I was designed and manufactured in accordance with international standards. I successfully passed all required tests. I have the permissions of the Turkish Ministry of Health, the quality safety system (CE) and quality management system (ISO 13485) certificates of international certification bodies and service qualitication certificate of Turkish Standards Institute and the EN 1789 standard for crash testing in ambulances.

7 Continuous and effective CPR...

I eliminate individual insufficiencies caused by the performance and tiredness of emergency teams while providing CPR quality in accordance with the standards... I provide consistent and high-quality chest compressions...
I increase patients' chances of coming back to life...
CPR devices have been reported to increase blood flow towards the brain and provide higher $EtCO_2$ values compared to manual compressions.*

8 I am with you in any condition...

I can be easily carried by hand or on the shoulder with my flexible and shock-resistant carrying bag. The inner surface of my carrying bag is flexible and has a body that absorbs impacts.
The ergonomic body of my bag conserves me and my accessories safely until they are reused.

9 Technical support...

Regardless of the cause of the breakdown, the breakdown of the device that reaches our central service will be fixed within 48 hours by our service teams. In technical services that will last longer than 48 hours, replacement device support will be provided meeting the needs of your emergency response teams. There will be no unjust treatment during the technical service.

10 Continuing training...

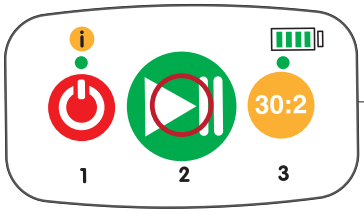
As the life-saving assistant of the emergency teams, we are always with you with face-to-face training, seminars, online device training, videos, literatures and scientific publications.

* Axelsson C, Karlsson T, Axelsson ÅB, et al. Mechanical active compression-decompression cardiopulmonary resuscitation (ACDCPR) versus manual CPR according to pressure of end tidal carbon dioxide (PETCO2) during CPR in out-of-hospital cardiac arrest (OHCA). Resuscitation. 2009;80(10):1099-103.

CEPER®

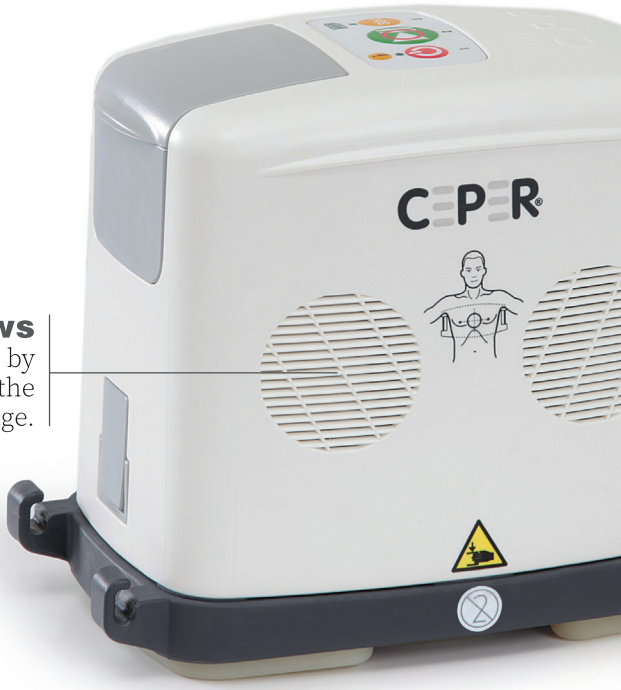
AUTOMATIC CPR CHEST COMPRESSION DEVICE

CEPER is used to provide prolonged and effective chest compressions at mechanically equal intervals in acute cardiac arrest patients accompanied by breathlessness, absence of pulse and loss of consciousness when CPR is required.



User control panel

It includes On/Off, Pause/Start, Continuously active / 30:2 active function buttons. Additionally, the battery level indicator and 2 visual warning lights guide the emergency team.



Ventilation windows

Prevent the device from heating by providing air circulation during the applied long-term massage.

Charger adapter

It is connected to the 220 V network line.
Outlet: 32 V

Belt buckle

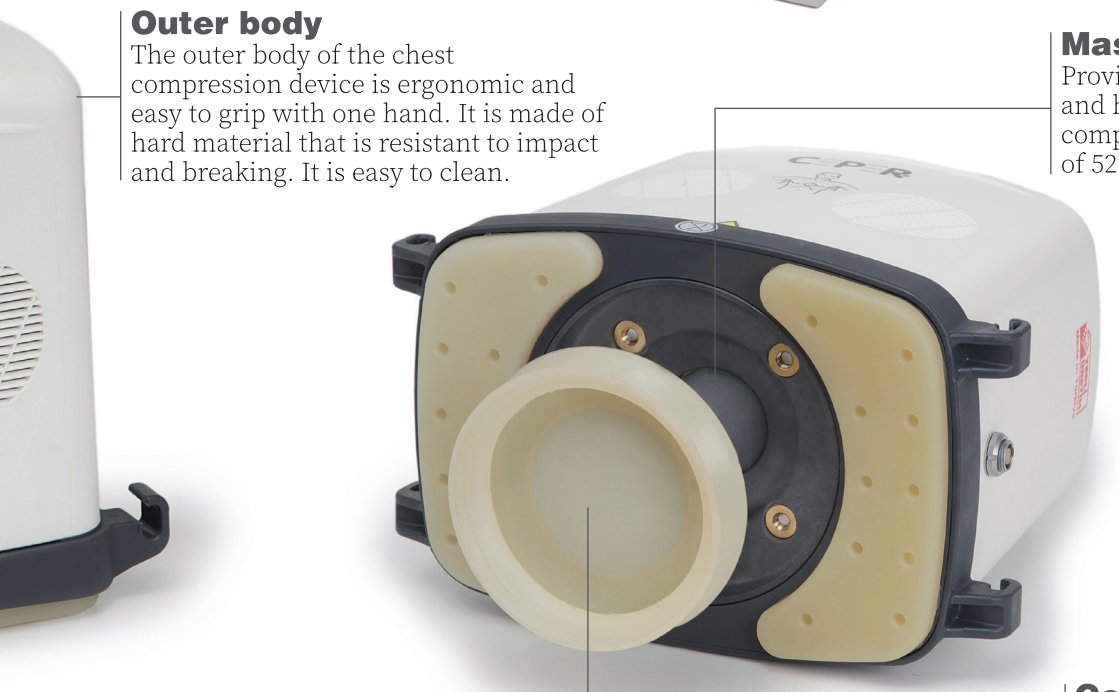
Buckles are attached to both ends of the back belt. Buckles immobilizes the adjustable back and shoulder belt to the device.

Charger
It charges the lithium-ion battery in 120 minutes.

Lithium ion battery
The usage time of a fully charged battery is minimum 60 minutes. Three batteries are supplied with the device.

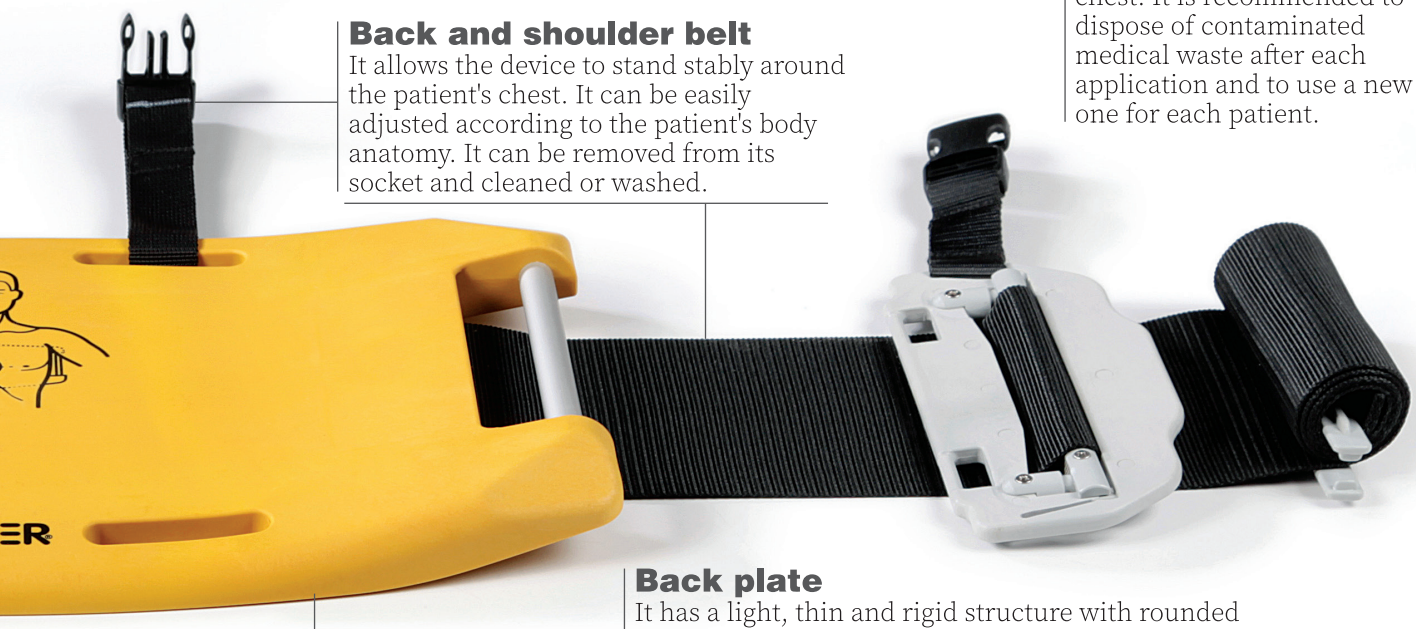
Outer body
The outer body of the chest compression device is ergonomic and easy to grip with one hand. It is made of hard material that is resistant to impact and breaking. It is easy to clean.

Massage plunger
Provides effective, consistent and high-quality chest compressions at a fixed depth of 52 mm.



Compression silicone
Ensures that the massage piston pressure is softened and absorbed in the patient's chest. It is recommended to dispose of contaminated medical waste after each application and to use a new one for each patient.

Back and shoulder belt
It allows the device to stand stably around the patient's chest. It can be easily adjusted according to the patient's body anatomy. It can be removed from its socket and cleaned or washed.



Back plate
It has a light, thin and rigid structure with rounded corners and edges, compatible with the human body anatomy. The back plate is ergonomic. It is easy to clean.

CEPER1®

AUTOMATIC CPR CHEST COMPRESSION DEVICE

Carrying bag and its contents

- 1 ergonomic carrying bag.
- 1 CEPER1 Automatic CPR Chest Compression device.
- 1 full back plate.
- Three rechargeable Lithium Ion batteries.
- Three single-use compression silicones.
- 1 external battery charger.
- 1 charger adapter.
- 1 user manual.
- 1 rapid use brochure.
- 1 set of CEPER battery charging chart.

Technical Specifications

Patient and Compression parameters

Compression depth	: 52 mm (+/– 2 mm) of compression depth is delivered.
Compression frequency	: 110 (+/– 4) compressions per minute.
Treatable chest sizes	: Suitable for patients whose chest circumference is between 76 cm and 135 cm.
Operating Mode	: Continuous mode: Delivers compression continuously. 30:2 mode: Performs 30 compressions, then pauses for three seconds for ventilation.

Technical specification of the device

Weight of the device	: Without battery: 3.2 kg, with battery: 3.75 kg
Full weight of the bag	: 9.25 kg
Device expiry time	: 10 years
Operation temperature	: –20°C - +50°C
Storing temperature	: –20°C - +50°C
Carrying and storage temperature	: –20°C - +50°C
IP class	: IP 42
Energy requirement	: 29V

Physical and operation specifications of the battery

Dimensions	: H: 13,5 x W: 7,5 x L: 7,5 cm
Weight	: 0.55 kg
Type	: Rechargeable Lithium-Ion battery (Li–on)
Charging time of the battery	: 120 min (maximum)
Operation temperature	: –20°C - +50°C

Evaluation of chest deformity, return of spontaneous circulation and 28-day survival rates after CPR with chest compression device in patients admitted to the emergency department due to cardiac arrest

O.F. Aydin[1], E. Gokdag[2], O. Canacik[3], C. Celik[3]
1. TC İstanbul Yeni Yüzyıl Üniversitesi, 2. Üsküdar Üniversitesi, 3. Şişli Memorial Hastanesi

Cardiac arrest (CA) is a serious threat to human health. Cardiopulmonary resuscitation (CPR) is an effective treatment for CA. Early and high-quality CPR is closely associated with the survival rate of patients with CA. However, manual application of chest compressions has some handicaps. Over time, mechanical CPR devices have been invented to solve these problems and improve CPR quality.

In our case-series report, we use a chest compression device CEPER© it has produced in Turkey with domestic and national capital. It applies 5.2 mm chest compressions 110±2 times per minute. We use the device for treatment of the patients who were admitted to the etmergency department due to cardiac arrest between 01 March and 31 August 2022. In total, 48 of 55 patients were suitable for chest compression device use.

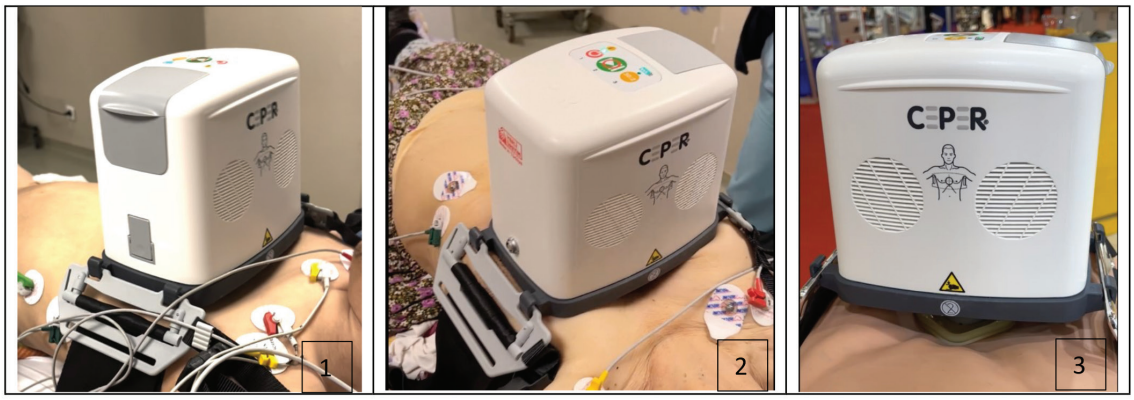


Table 1. figure 1 and 2: Using CEPER chest compression device on patients. 3: Using CEPER on Adult CPR model

We evaluated the patients according to their gender and age groups. We also grouped them according to the causes of arrest. Here, we considered the last situation that led to the development of cardiac arrest in the patient. In prehospital cases; we examined the duration of arrest and the duration of prehospital CPR after the first aid teams arrived. We also examined the prehospital airway management and intubation status of the patients. We measured the waiting times, intubation status, and the time to apply chest compressions and CPR from the moment they arrived at the hospital as a pre-hospital arrest. The data we obtained as a result of the evaluation made us think that the probability of return of spontaneous circulation may increase as the waiting time of patients in prehospital arrest decreases and the rate of successful tracheal intubation increases.

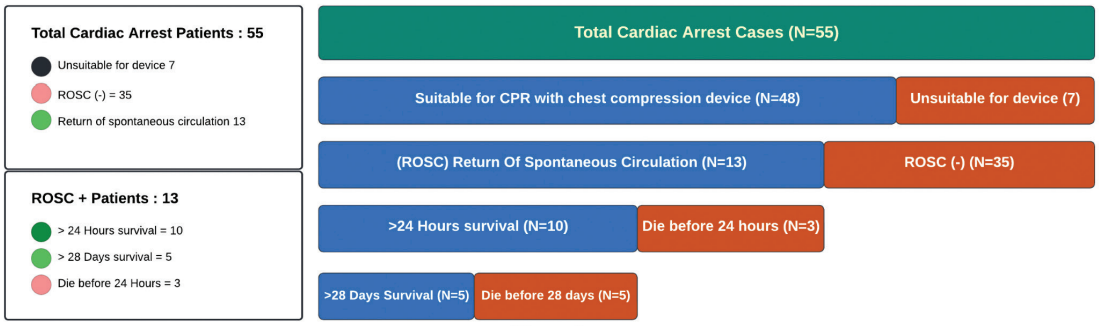


Figure 1:
General evaluation diagram of the study;
The total number of patients is 55. 48 of these patients were found suitable for chest compression device application. Survival rate of more than 28 days was observed in 5 patients out of a total of 13 patients with spontaneous return of circulation.

For full text, please scan the QR code.

CERTIFICATE

kiwa

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-830

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

Remar Medikal Cihazlar Sanayi ve Ticaret Anonim Şirketi

Mahmutbey Mah. Taşocağı Yolu Cad. No:7/1/1B1 Bağcılar/İstanbul- Turkey

Product: Automatic CPR Chest Compression Device
Model: CEPER1

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.6051.01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

22 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

kiwa

REMAR MEDİKAL CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ

Mahmutbey Mah. Taşocağı Yolu Cad. No: 7/1/1B1 Bağcılar - İstanbul - Turkey

Design, Manufacture, Sales and Marketing Activities and After-Sales Service of Automatic CPR Chest Compression Device

with a scope of

EN ISO 13485:2016

Has established a management system in accordance with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.3" "7.5.5" "7.5.7" "7.5.9.2"

Certificate No	: M 11622
Initial Certification Date	: 27 May 2021
Certification Date	: 27 May 2021
Expiration Date	: 26 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

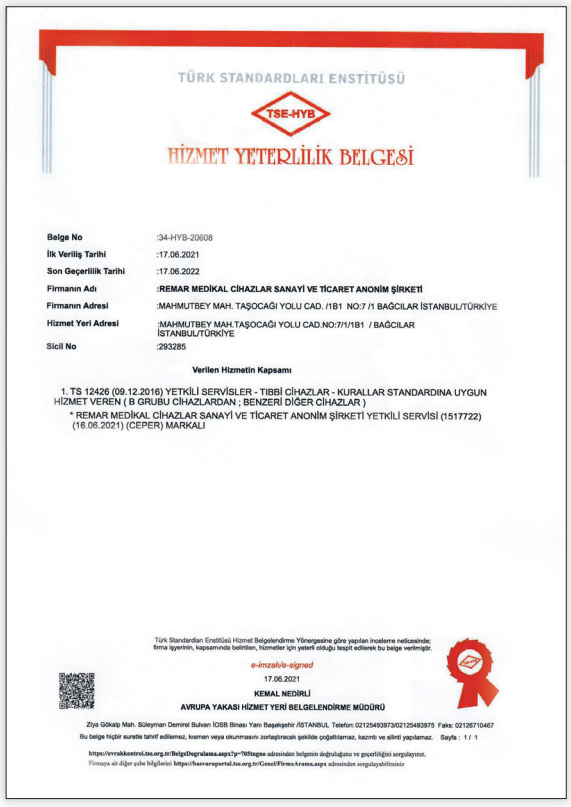
Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

General Manager

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK BGS NO
YS-4F5D-DFE2

Last Modified: 27 May 2021 - R 00



TÜRK STANDARDLARI ENSTİTÜSÜ

TSE-HYB

HİZMET YETERLİLİK BELGESİ

Belge No	:34-HYB-20608
İlk Veriliş Tarihi	:17.06.2021
Son Geçerlilik Tarihi	:17.06.2022
Firmanın Adı	:REMAR MEDİKAL CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ
Firmanın Adresi	:MAHMUTBEY MAH. TAŞOCAĞI YOLU CAD. /1B1 NO:7 /1 BAĞCILAR İSTANBUL/TÜRKİYE
Hizmet Yeri Adresi	:MAHMUTBEY MAH.TAŞOCAĞI YOLU CAD.NO:7/1/1B1 / BAĞCILAR İSTANBUL/TÜRKİYE
Sicil No	:293285

Verilen Hizmetin Kapsamı

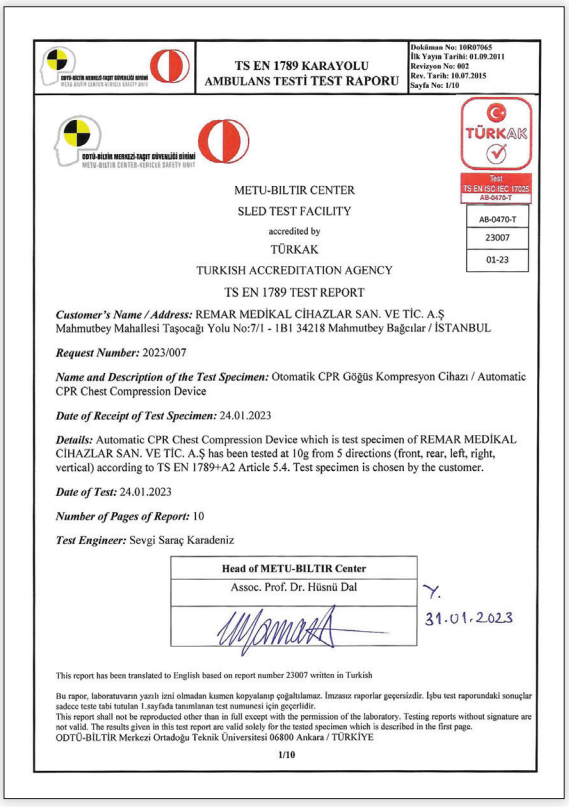
1. TS 12426 (09.12.2016) YETKİLİ SERVİSLER - TIBBİ CİHAZLAR - KURALLAR STANDARDINA UYGUN HİZMET VEREN (B GRUBU CİHAZLARDAN ; BENZERİ DİĞER CİHAZLAR)
* REMAR MEDİKAL CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ YETKİLİ SERVİSİ (1517722) (16.06.2021) (CEPER) MARKALI

Türk Standardları Enstitüsü Hizmet Belgelendirme Yönergesine göre yapılan incelerne neticesinde; firma işyerinin, kapsamında belirtilen, hizmetler için yeterli olduğu tespit edilerek bu belge verilmiştir.

e-imzalı/e-signed
17.06.2021
KEMAL NEDİRLİ
AVRUPA YAKASI HİZMET YERİ BELGELENDİRME MÜDÜRÜ

Ziya Gökalp Mah. Süleyman Demirel Bulvarı İOSB Binası Yanı Başakşehir /İSTANBUL Telefon: 02125493973/02125493975 Faks: 02126710467
Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazınti ve silinti yapılamaz. Sayfa : 1 / 1

https://evraklkontrol.tse.org.tr/BelgeDogrulama.aspx?y=765tsgse adresinden belgenin doğruluğunu ve geçerliliğini sorgulayınız.
Firmaya ait diğer yetki bilgilerini https://basvuruportal.tse.org.tr/CeserFirmaArama.aspx adresinden sorgulayabilirsiniz



TS EN 1789 KARAYOLU AMBULANS TESTİ TEST RAPORU

Doküman No: 10R07065
İlk Yayın Tarihi: 01.09.2011
Revizyon No: 002
Rev. Tarih: 10.07.2015
Sayfa No: 1/10

TÜRKAK
Test
TS EN ISO IEC 17025
AB-0470-T

AB-0470-T
23007
01-23

METU-BILTIR CENTER
SLED TEST FACILITY
accredited by
TÜRKAK
TURKISH ACCREDITATION AGENCY

TS EN 1789 TEST REPORT

Customer's Name / Address: REMAR MEDİKAL CİHAZLAR SAN. VE TİC. A.Ş
Mahmutbey Mahallesi Taşocağı Yolu No:7/1 - 1B1 34218 Mahmutbey Bağcılar / İSTANBUL

Request Number: 2023/007

Name and Description of the Test Specimen: Otomatik CPR Göğüs Kompresyon Cihazı / Automatic CPR Chest Compression Device

Date of Receipt of Test Specimen: 24.01.2023

Details: Automatic CPR Chest Compression Device which is test specimen of REMAR MEDİKAL CİHAZLAR SAN. VE TİC. A.Ş has been tested at 10g from 5 directions (front, rear, left, right, vertical) according to TS EN 1789+A2 Article 5.4. Test specimen is chosen by the customer.

Date of Test: 24.01.2023

Number of Pages of Report: 10

Test Engineer: Sevgi Saraç Karadeniz

Head of METU-BILTIR Center
Assoc. Prof. Dr. Hüsnü Dal

Y.
31.01.2023

This report has been translated to English based on report number 23007 written in Turkish

Bu rapor, laboratuvarın yazılı izni olmadan kısmen kopyalanıp çoğaltılamaz. İmzasız raporlar geçersizdir. İşbu test raporundaki sonuçlar sadece teste tabi tutulan 1.sayfada tanımlanan test numunesi için geçerlidir.
This report shall not be reproduced other than in full except with the permission of the laboratory. Testing reports without signature are not valid. The results given in this test report are valid solely for the tested specimen which is described in the first page.
ODTÜ-BİLTİR Merkezi Ortadoğu Teknik Üniversitesi 06800 Ankara / TÜRKİYE

1/10

REMAR®
MEDİKAL CİHAZLAR SAN. VE TİC. A.Ş.

Mahmutbey Mahallesi, Taşocağı
Yolu Caddesi, No: 7/1 - 1B1
34218 Bağcılar - İstanbul / Türkiye
Tel : +90 (212) 446 38 38 PBX
Fax : +90 (212) 446 38 39-40
Web : www.remarmedikal.com
e-mail : rk@remarmedikal.com