OKUMAN Healthcare

Dedicated Hospital Solutions

DFM600

DEFIBRILLATOR/MONITOR

Digitally signed by Bolea Petru
Date: 2023.04.17 09:37:42 EEST
Reason: MoldSign Signature
Location: Moldova

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Standard Configuration
ECG, RESP, Thermal Recorder

Optional
NIBP, TEMP, PR, $EtCO_2$, IBP, SPO_2

Safety Standards
ISO 13485:2016 approved, CE marking according to MDD93/42/EEC

Physical Characteristics

Size:	323mm×277mm×338mm
Weight:	7.2 kg
Screen Size:	8.4" TFT touch screen
Resolution:	800 × 600
Waveforms:	4 waveforms

Operation Environment

Temperature:	0~45°C
Humidity:	10%~95%, non-condensation
Water Resistance:	IP44 (without external power)
Solids Resistance:	IP4X
Power requirement:	100-240V~, 50/60Hz±1Hz
Battery type:	Rechargeable Lithium-ion battery
Battery capacity:	7500mAh, d.c.14.8V
Battery number:	Max 2
Battery recharging Time:	Less than 2 hours to 80% and less than 3 hours to 100% with equipment power off
Battery backup: (Two new, fully charged battery)	Monitoring Mode: 12 hours; Defib Mode: 420 times (360J charge at intervals of 1minute without recording); Pacing Mode: 9 hours (50 Ω load impedance, Pacing rate: 80bpm, Pacing output: 60mA, without recording)
Brightness:	Manual from 1 to 10

Indicator

Two alarm indicators
Power indicator
Battery indicator
Maintain indicator
Error indicator
QRS beep and alarm sound
Operating key sound

Interfacing

USB interface
RJ45 interface
AC power input
VGA interface
Multi-functional connector

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Date storage

Alarm Event:	200 groups
Patient profiles:	1000 groups
Wave Review:	48 hours
NIBP Review:	2000 groups
Trend Graph:	160 hours
Trend Table:	160 hours
ECG report:	500 cases of 12-lead ECG diagnosis report (Up to 5 case reports per patient)
Voice recording:	Max 240 min in total; (Up to 60 min for each patient)
Marked events:	Available
Power-off storage:	Yes
Alarm:	User-adjustable High and Low 3-level Limits; Prioritized audible and visual alarm
Network:	Connected to Central Monitoring System by hardwire/wireless

Recorder

Type:	Built-in; Thermal array
Channel:	4 channel waveforms
Real-time recording:	3s, 5s, 8s, 16s, 32s, auto
Speed:	25mm/s, 50mm/s
Record width:	80mm
Resolution:	8dot/mm (Horizontal and vertical)
Background grid:	Configurable

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Defibrillator

Operating mode:	Manual Mode, AED Mode, Synchronous defibrillation
Waveform:	Biphasic truncated exponential waveform, with impedance compensation
Defibrillation pathway:	External defibrillation & Internal defibrillation
Electrode type:	External defibrillation electrode plate, multifunctional electrode pads and internal defibrillation electrode plate
External defibrillation electrode plate:	Supports charging, discharging, energy selection and other operational functions; Charging completion indicator
Charge Time: (Battery power)	Less than 5 seconds to 200 Joules with a new, fully charged battery Less than 8 seconds to 360 Joules with a new, fully charged battery
Energy accuracy:	±1.5J or ±10% of setting, whichever is greater, into 50Ω ±2J or 15% of setting, whichever is greater, into 25Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω,
Patient Impedance Range:	25~300Ω(External defibrillation); 15~250Ω(Internal defibrillation)
Defibrillation proof:	Type CF: ECG, RESP, SpO_2, NIBP, IBP, TEMP, PR; Type BF: CO_2

Manual Mode

External defibrillators:	1J~360J
Internal defibrillation:	1J~50J
Synchronous Cardioversion:	Energy transfer begins within 60ms of the QRS peak; Energy transfer begins within 25ms of the External Sync signal

AED

Output Energy:	User configurable
AED Shock Series:	Configurable

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Noninvasive Pacing

Waveform:	Monophasic square wave pulse
Pulse Width:	20 ms
Accuracy:	±5%
Pacing Mode:	Demand or fixed
Pacing rate:	40 ppm to 170 ppm
Accuracy:	±1ppm or ±1.5% (whichever is greater)
Pacing output:	0 mA to 200 mA
Accuracy:	±5% or ±5mA, whichever is greater
4:1 pacing:	Pacing pulse frequency reduced by factor of 4 when activated

Monitoring ECG

Lead Type:	3 lead ECG, 5 lead ECG, 12 leads ECG, AUTO
Lead selection:	12-Lead I; II; III; aVR; aVL;aVF; V1~V6 5-lead: I; II; III; aVR; aVL; aVF; V 3-lead: I; II; III
Multi-lead synchronization analysis:	Available ECG size: Auto, 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4),
Accuracy:	Less than ±5%
Sweep speed:	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Accuracy:	Less than ±10% Heart Rate
Measurement& alarm range:	Adult: 15~300bpm Pediatric/Neonate: 15~350bpm
Resolution:	1 bpm
Accuracy:	±1% or ±1bpm (whichever is greater)
Bandwidth:	MON: 0.5~40Hz DIA: 0.05~150Hz Treat: 1~20Hz ST: 0.05~40Hz
CMRR:	MON: >105dB DIA: >90dB Treat: >105dB ST: >105dB
Input Impedance:	≥5MΩ
Input signal range:	±8mV
HR trigger value:	200μV
Lead off detection current:	Measuring electrode: <0.1μV Driving electrode: <1μV
Pacemaker pulse suppression switch:	Manual selection when the pacemaker is turned on
Analog output:	Magnification: 1:1000; Accuracy: ±5% Bandwidth: 0.5Hz~40Hz Delay: ≤35ms
ST Detection:	-2.0mV~+2.0mV

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Resolution:	0.01mV
Accuracy:	-0.8mV ~ +0.8mV: ±0.02mV or ±10%; Others: Unspecified
System noise:	Less than 25μV
Calibration voltage:	1 mV;
Accuracy:	±5%
Arrhythmia Analysis:	26 Types
Pacemaker detection:	Detectable

Defibrillation ECG

Lead Type:	Single lead ECG
Heart Rate measurement& alarm range:	Adult: 15~300bpm Pediatric/Neonate:15~350bpm
Resolution:	1 bpm
Accuracy:	±1% or ±1bpm (whichever is greater)
Bandwidth:	Defib: 1~20Hz
CMRR:	Defib: >105dB
Input Impedance:	≥5MΩ
Input signal range:	±8mV
HR trigger value	200μV
Arrhythmia Analysis:	5 Types

Respiration

Method:	RA-LL Impedance Method
RR measurement range:	Adult: 0~120rpm Pediatric/Neonate: 0 ~150bpm
Accuracy:	7~150rpm: ±2rpm or ±2% (whichever is greater) 0~6rpm: unspecified
Apnea Alarm:	Adult: 10s~60s Ped/Neo: 10s~40s
Accuracy:	±5s
Alarm:	Audible and visual alarm; alarm events reviewable

NIBP

Method	Automatic oscillometric
Work mode:	Manual / Automatic/Continuous
Measurement Time:	Adjustable (1~720min)
Maximum measurement time:	Adu/Ped: 120s; Neo: 85s
Measurement Unit:	mmHg / kPa selectable
Measurement types:	Systolic, Diastolic, Mean
Range of systolic pressure:	Adult Mode:40~270mmHg Pediatric Mode:40~200mmHg Neonate Mode 40~135mmHg
Range of diastolic pressure:	Adult Mode:10~215mmHg Pediatric Mode:10~150mmHg Neonate Mode 10~100mmHg
Range of mean pressure:	Adult Mode:20~235mmHg Pediatric Mode:20~165mmHg Neonate Mode 20~110mmHg
Over pressure protection:	Both Hardware and software over pressure protection
Accuracy:	±3mmHg
Resolution:	1 bpm
Alarm:	Systolic, Diastolic, Mean PR from

Nellcor SpO_2

Measurement range:	0~100%
Resolution:	1%
Accuracy:	±2% (70~100%, Adu/Ped, non- motion) ±3% (70~100%, Neo, non-motion) 1~69% unspecified
Alarm range:	20~100%
PR Measurement Range:	20~300bpm
Resolution:	1bpm
Accuracy:	±3bpm (20~250bpm) Unspecified (251~300bpm)
Alarm range:	20~350bpm

Masimo SpO_2

Measurement&alarm range:	1~100%
Resolution:	1%
Accuracy:	±2% (70~100%, Ped/Adu, non-motion) ±3% (70~100%, Neo, non-motion); 1~69% unspecified
Alarm range	1~100%
PR Measurement Range:	25~240bpm
Resolution:	1bpm
Accuracy:	±3%(non-motion) ±5% (motion);
Alarm range:	20~350bpm
PI value: Resolution:	0.02~20% 0.01% (0.02%~9.99%) 0.1% (10.0%~20.0%)
Accuracy:	Unspecified
SIQ:	Available

Okuman SpO_2

Measurement&alarm range:	0~100%
Resolution:	1%
Accuracy:	±2% (70~100%, Ped/Adu, non-motion) ±3% (70~100%, Neo, non-motion); 0~69% unspecified
PR Measurement Range:	20~254bpm
Resolution:	1bpm
Accuracy:	±2bpm
Alarm range:	20~350bpm
PI value:	0.05~20%
Resolution:	0.01% (0.05%~9.99%) 0.1% (10.0%~20.0%)
Accuracy:	Unspecified
SIQ:	Available

Temperature (Dual Channel)

Measurement & alarm range:	0~50°C
TEMP sensor:	Standard configuration- skin TEMP sensor
Resolution:	0.1°C
Accuracy:	±0.1°C (except sensor error)
Channel type:	T1, T2, TD (Temperature Difference)

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MASIMO $EtCO_2$ (Sidestream)

Measurement range:	0~190mmHg, 0~25% (at 760mmHg)
Accuracy:	± (2.25mmHg +4% of reading)
Resolution:	1mmHg
awRR range:	0~150rpm
awRR accuracy:	±1rpm
Response time:	<240msec (10% to 90%)
Delay time:	<2s

Respironics $EtCO_2$ (Sidestream)

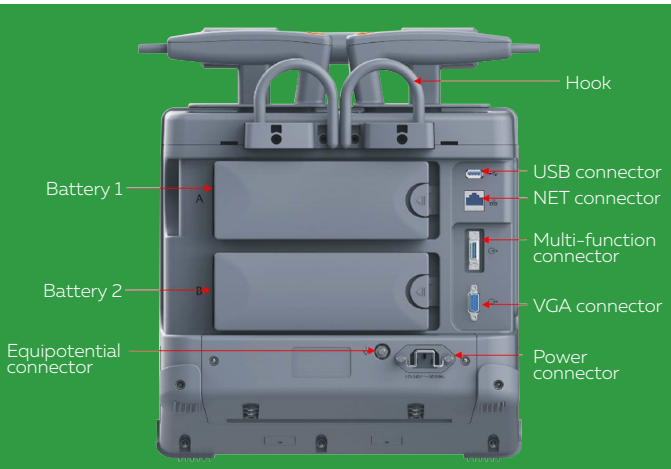
Measurement range:	0~150mmHg, 0to 25% (at 760mmHg)
Accuracy:	± 2 mmHg (0 – 40 mmHg) ± 5% of reading (41 – 70 mmHg) ± 8% of reading (71 –100 mmHg) ±10% of reading (101~150 mmHg)
Resolution:	1mmHg
awRR range:	0~150rpm
awRR accuracy:	±1rpm
Response time:	<240msec (10% to 90%)
Delay time:	<2s

IBP

Channel:	2 Channels
Measured Pressure:	ART, PA, CVP, RAP, LAP, ICP, LV, AO, UAP, BAP, FAP, UVP, IAP, P1, P2, P3, P4
Measurement Unit:	mmHg/ kPa/ cmH2O selectable
Measurement range:	ART: 0~300mmHg PA: -6~120 mmHg CVP: -10~40mmHg RAP: -10~40mmHg LAP: -10~40mmHg ICP: -10~40mmHg LV: 0~300mmHg AO: 0~300mmHg UAP: 0~300mmHg BAP: 0~300mmHg FAP: 0~300mmHg UVP: -10~ 40mmHg IAP: -10~40mmHg P1, P2: -50~300mmHg
Accuracy:	±2% or ±1mmHg (whichever is greater)
Resolution:	0.1kPa or 1mmHg (-50mmHg~+300mmHg)
Alarm Range:	-50mmHg~+300mmHg
PR from IBP:	20bpm~350bpm
Resolution:	1bpm
Accuracy:	±1% or ±1bpm, whichever is greater
PPV/SPV measurement:	Available

External Paddle (Adult-Child)


Smart Battery



Back View of DFM 600

OKUMAN Medikal Sistemler A.Ş.
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ISO 13485

ISO 9001

Catalog ID: DFM 600 003-092021-EN

DEFİBRİLATÖR MONİTÖR AT UYGUNLUK BEYANI

DEFIBRILLATOR MONITOR EC DECLARATION OF CONFORMITY

Bu ürünlerin "OKUMAN" markalı olarak Tıbbi cihaz Yönetmeliği (93/42/EEC) ve 2007/47/EEC gereklerini karşılayacak şekilde ürettiğimizi ve ürünlerin bizim sorumluluğumuzda olduğunu beyan ediyoruz. Tüm destekleyici dokümanlar üreticide tutulmaktadır. Bu ürünler hakkındaki beyanımız aşağıdaki harmonize standartlara veya örnek oluşturan belgelere uygun olduğu hakkındadır.

We declare that these products are manufactured under the brand of "OKUMAN" in accordance with the requirements of the Medical Device Directive (93/42 / EEC) and 2007/47 / EEC and that the products are under our responsibility. All supporting documents are retained at the premisses of the manufacturer. This decleration about the products, is related to the following harmonised standards or other normative documents.

Üretici: ***Manufacturer:***	Okuman Medikal Sistemler Anonim Şirketi
Adres: ***Adress:***	Zübeyde Hanım Mahallesi Kazım Karabekir Caddesi No:95/90 06060 İskitler, Ankara, TÜRKİYE (TURKEY)
Fabrika Adres: ***Factory Adress:***	İvedik Organize Sanayi Bölgesi Arı Sanayi Sitesi 1. Etap 1417. Sokak No:51 Yenimahalle, Ankara, TÜRKİYE (TURKEY)
Telefon/Faks/e-Posta: ***Phone/Fax/e-Mail:***	+90 (312) 384 0520/ +90 (312) 384 1975/ info@okuman.com.tr

Ürün Tanımı: ***Product Description:***	Defibrilatör Monitör *Defibrillator Monitor*
Model Numarası: ***Model Number:***	DFM 600/ DFM 800
Tıbbi Cihaz Sınıfı/Kuralı: ***Classification:***	IIb/ MDD (93/42/EEC) Ek IX- Kural IX *IIb/ MDD (93/42/EEC) Annex IX- Rule IX*
GMDN kodu: ***GMDN code:***	17882
Uygunluk Değerlendirme Yolu: ***Conformity of Assessment:***	MDD (93/42/EEC) Ek II Bölüm III MDD (93/42/EEC) Annex II Section III
Onaylanmış Kuruluş: ***Notified Body:***	KİWA BELGELENDİRME HİZMETLERİ A.Ş.
Adres: ***Adress:***	ITOSB 9. Cadde No:15 Tepeören Tuzla, İstanbul, TÜRKİYE (TURKEY)
Onaylanmış Kuruluş No: ***Notified Body No:***	1984
EC Sertifika No: ***EC Certificate No:***	1984-MDD-17-428
Son Geçerlilik Tarihi: ***Expiry Date:***	27.05.2024

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Uyumlu Olunan Harmonize Standartlar: Aşağıda listelendiği gibidir.
Applied harmonised standards: *Listed below.*

Standart No:	**Standart Adı/ *Standard Name:***
TS EN ISO 13485: 2016	Tıbbî cihazlar - Kalite yönetim sistemleri - Mevzuat amaçları bakımından şartlar *Medical devices Quality Management Systems Requirements for Regulatory Purposes*
EN ISO 14971: 2012	Tıbbi Cihazlar- Tıbbi Cihazlarda Risk Yönetimin Uygulanması *Medical devices - Application of risk management to medical devices*
MEDDEV. 2.7.1 Rev.4: 2016	Klinik Değerlendirme: Üreticiler ve Onaylanmış Kuruluşlar İçin Kılavuz *Clinical Evaluation:A Guide For Manufacturers And Notified Bodies*
MEDDEV. 2.12-1 Rev.8: 2013	Tıbbi Cihazlar Uyarı Sistemi Hakkında Kılavuzlar *Guidelines On A Medical Devices Vigilance System*
MEDDEV. 2.12-2 Rev.2: 2012	Post Market Clınıcal Follow-Up Studıes A Guıde For Manufacturers And Notified Bodies
TS EN ISO 15223-1: 2016	Tıbbi cihazlar - Tıbbi cihaz etiketlerinde, etiketlemede ve sunulacak bilgide kullanılacak semboller - Bölüm 1: Genel özellikler *Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements*
TS EN1041+A1: 2014	Tıbbi cihazlarla birlikte imalatçı tarafından sağlanan bilgiler *Information supplied by the manufacturer of medical devices*
TS EN60601-1/A1: 2014	Elektrikli tıbbi donanım - Bölüm 1:Temel güvenlik ve gerekli performans için genel kurallar *Medical electrical equipment; Part 1: General requirements for safety*
TS EN60601-1-2: 2016	Elektrikli tıbbî cihazlar - Bölüm 1: Genel güvenlik kuralları - Kısım 2: Tamamlayıcı standard: Elektromanyetik uyumluluk - Kurallar ve deneyler *Medical electrical equipment Part 1: General requirements for safety -2 Collateral standard: Electromagnetic compatibility - Requirements and tests*
TS EN 60601-1-6/A1:2015	Elektrikli tıbbi donanım - Bölüm 1-6: Temel güvenlik ve gerekli performans için genel kurallar - Yardımcı standard: Kullanım Kolaylığı *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
TS EN 60601-1-8/A11:2017	Elektrikli tıbbi donanım - Bölüm 1-8: Temel güvenlik ve gerekli performans için genel kurallar - Yardımcı standard: Elektrikli tıbbi donanım ve elektrikli tıbbi sistemlerdeki uyarı sistemleri için genel özellikler, deneyler ve rehber *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm*

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	systems in medical electrical equipment and medical electrical systems
TS EN 62304/A1:2016	Tıbbi cihaz yazılımı - Yazılım yaşam çevrimi süreçleri *Medical device software - Software life-cycle processes*
TS EN 62366-1/AC: 2016	Tıbbi cihazlar - Bölüm 1: Kullanılabilirlik tekniğinin tıbbi cihazlara uygulanması *Medical devices - Application of usability engineering to medical devices*
TS EN ISO10993-1/AC:2014	Tıbbi cihazların biyolojik değerlendirilmesi - Bölüm 1: Bir risk yönetim sürecinde değerlendirme ve deney *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)*
TS EN ISO 10993-5:2010	Tıbbî cihazların biyolojik değerlendirmesi - Bölüm 5: Vücut dışı (ın vitro) sitotoksisite deneyleri *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
TS EN ISO 10993-10:2014	Tıbbî cihazların biyolojik değerlendirilmesi - Bölüm 10: Tahriş ve cilt duyarlılığı için deneyler (ISO 10993-10:2010) *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization(ISO 10993-10:2010)*
TS EN 60601-2-4/A1:2019	Elektrikli tıbbî donanım - Bölüm 2-4: Kalp defibrilatörlerinin temel güvenliğive önemli performansı için belirli özellikler *Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators*
TS EN 60601-2-27: 2014	Elektrikli tıbbi donanım - Bölüm 2-27: Elektrokardiyografik izleme donanımının gerekli performansı ve güvenliği için belirli özellikler *Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment*
TS EN IEC 80601-2-30: 2019	Elektrikli tıbbi donanım - Bölüm 2-30: Girişimsel olmayan otomatik tekrarlı kan basıncı izleme donanımının gerekli performansı dâhil güvenlik için belirli özellikler *Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*
TS EN IEC 80601-2-49: 2019	Elektrikli tıbbi donanım - Bölüm 2-49: Çok fonksiyonlu hasta izleme cihazının temel güvenliği ve gerekli performansı için belirli özellikler *Medical electrical equipment - Part 2-49 Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*
TS EN ISO 80601-2-61:2019	Elektrikli tıbbi donanım -Bölüm 2-61:Puls oksimetre donanımının gerekli performansı ve temel güvenliği için belirli özellikler *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

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TS EN ISO 80601-2-55:2018	Elektrikli tıbbi donanım - Bölüm 2-55:Solunum gaz monitörlerinin temel güvenliği ve gerekli performansıyla ilgili belirli özellikler *Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
TS EN 1789+A2: 2015	Tıbbi araçlar ve donanımları - Kara yolu ambulansları *Medical Vehicles and Their Equipment - Road Ambulances*

Yer ve Yayın Tarihi: ANKARA- 14.10.2021
Place and Date of Issue:

Onaylayan: Ogan UÇAK
Confirm:

CERTIFICATE

OKUMAN MEDİKAL SİSTEMLER ANONİM ŞİRKETİ

HQ; ZÜBEYDE HANIM MAHALLESİ KAZIM KARABEKİR CADDESİ 95/95 06060
ALTINDAĞ - ANKARA - TÜRKİYE
FACTORY; İVEDİK ORGANİZE SANAYİ BÖLGESİ ARI SANAYİ SİTESİ 1417 SOKAK NO: 51
YENİMAHALLE - ANKARA - TÜRKİYE

Production of Intensive Care Phototherapy Device, Radiant Warmer, Infant Incubators, Multi-parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Resuscitation Device, Distribution, Sales and After Sales Services of Respiratory Devices, Anesthesia Devices, Respiratory Function Test Devices, Fetal Monitors, Pulse Oximeters, Infusion and Syringe Pumps, Pressure Transducers, Operating Tables and Lamps, Laryngoscopes, ECG Devices, Sedation Devices, Intensive Care Phototherapy Device, Radiant Warmer, Infant Incubators, Multi-Parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Air/Oxygen Blender and their accessories

with a scope of

ISO 9001:2015

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "
"None"

Certificate No	: M 8159
Initial Certification Date	: 15 September 2010
Certification Date	: 02 September 2022
Expiration Date	: 01 September 2025

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 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

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

TÜRKAK BDS NO
YS-BA29-93D0

Last Modified : 02 September 2022 - R 09

CERTIFICATE

OKUMAN MEDİKAL SİSTEMLER ANONİM ŞİRKETİ

HQ; ZÜBEYDE HANIM MAHALLESİ KAZIM KARABEKİR CADDESİ 95/95 06060
ALTINDAĞ - ANKARA - TÜRKİYE
FACTORY; İVEDİK ORGANİZE SANAYİ BÖLGESİ ARI SANAYİ SİTESİ 1417 SOKAK NO: 51
YENİMAHALLE - ANKARA - TÜRKİYE

Production of Intensive Care Phototherapy Device, Radiant Warmer, Infant Incubators, Multi-parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Resuscitation Device, Distribution, Sales and After Sales Services of Respiratory Devices, Anesthesia Devices, Respiratory Function Test Devices, Fetal Monitors, Pulse Oximeters, Infusion and Syringe Pumps, Pressure Transducers, Operating Tables and Lamps, Laryngoscopes, ECG Devices, Sedation Devices, Intensive Care Phototherapy Device, Radiant Warmer, Infant Incubators, Multi-Parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Air/Oxygen Blender and their accessories

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"
"7.5.5" "7.5.7" "7.5.9.2"

Certificate No	: M 8160
Initial Certification Date	: 15 September 2010
Certification Date	: 02 September 2022
Expiration Date	: 01 September 2025

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
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Tel: + 90 216 593 25 75
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Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK Medical Devices TS EN ISO 13485: 2016 AB-0006-YS
TÜRKAK BDS NO YS-EE82-2C33

Last Modified : 02 September 2022 - R 10

CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-17-428

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:

OKUMAN MEDİKAL SİSTEMLER ANONİM ŞİRKETİ

HQ: Zübeyde Hanım Mahallesi Kazım Karabekir Caddesi No:95/95
06060 İskitler, Ankara, Turkey
Factory: İvedik Organize San. Bölgesi Arı Sanayi Sitesi 1.Etap 1417 Sok.
No:51 Yenimahalle, Ankara, Turkey

Products: Intensive Care Phototerapy, Radiant Warmer, Infant Incubator, Multi-Parameter Patient Monitors, Infant Ventilator, Transport Incubator, Defibrillator Monitor, Warming Bed, Resuscitation Device

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

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Revision Number: 08
Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

22 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-17-428, Revision Number: 08
Concerned medical devices;

Product: Intensive Care Phototerapy
Model Number: BiliCare

Product: Radiant Warmer
Model Number: OKM 730

Product: Infant Incubator
Model Number: OKM 801, OKM 862

Product: Infant Ventilator
Model Number: OKM IBS

Product: Transport Incubator
Model Number: TR 203

Product: Multi-Parameter Patient Monitors
Model Number: OKM VS3, OKM 300, OKM 500, OKM 600, OKM 700, OKM 800, OKM 860, OKM 900, OKM 84, OKM 104, OKM 121, OKM 8800

Product: Defibrillator Monitor
Model Number: DFM600, DFM800

Product: Warming Bed
Model Number: OKM 740

Product: Resuscitation Device
Model Number: OKM 150

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

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OKUMAN
for Home Healthcare & Hospital Solution

OKUMAN Medikal Sistemler A.Ş.
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Letter of authorization

We, **OKUMAN MEDIKAL SISTEMLER A.S.**, who are official manufacturers of DEFIBRILLATOR, INFANT INCUBATOR, RADIANT WARMER and etc, having factories at IVEDIK OSB MAH. 1417 SOK NO 51 YENIMAHALLE, ANKARA, TURKEY, and head office in KAZIM KARABEKIR CAD 95/95 ISKITLER, ANKARA, TURKEY, do hereby authorize and entitle **Imunotehnomed Ltd, 42 Gh.Asachi str., MD-2028, Chisinau, Republic of Moldova** to import, promote and sell OKUMAN's product line throughout the territory of the Republic of Moldova.

As the authorized representative, in correspondence with the conditions of Directive 93/42/EEC (MDD 93/42/EEC), 98/79/EEC, 90/385/EEC, Regulation (EU) 2017/745, Regulation (EU) 2017/746, ***Imunotehnomed Ltd****, shall exercise all powers related to the process of placing medical devices on the market on behalf of the* ***OKUMAN MEDIKAL SISTEMLER A.S.****, in particular, but without limiting the generality of the foregoing, perform registration, renewal or any other variations of the registration with the National Competent Authority.*

Signed: 

Name: Anindya Guha

Title: Business Development Manager

Duly authorized to sign this Authorization on behalf of: OKUMAN MEDIKAL SISTEMLER A.S.

Dated on 12th day of April, 2023