



# ZU APOTEKE CRNE GORE MONTEFARM

Ljubljanska bb PODGORICA  
 Matični broj: 02017105  
 PDV broj: 20/31-00073-7  
 Šifra djelatnosti: 052310

Ž.r.: 535-4918-69  
 510-205-07  
 530-12751-75  
 550-4768-38

Prva Banka Crne Gore  
 Crnogorska Komercijalna Banka  
 Nib Banka  
 Podgorička Banka,

## OTPREMNICA-FAKTURA

OTPREMNICA BROJ: 2021000629  
 DATUM OTPREMNICE: 21.07.2021  
 SKLADIŠTE: SKLADIŠTE DONACIJA  
 BROJ TREBOVANJA:

KOMITENT: KLINIČKI CENTAR CG APOTEKA  
 Magacin KC

Rbr	Šifra Artikal / Šifra fonda	Rok	Seriya	Jm	Količina	Cijena	Rab%	PDV	Iznos
1	41386 Defibrilator 20e LifePak			kom	12.00	5,542.0000	100	0	.00
2	41387 Pacijent monitor C90 COMEN			kom	20.00	6,816.0000	100	0	.00

UKUPNI IZNOS RABATA: 202,824.00

UKUPNI IZNOS OSNOVICE: .00

UKUPNI IZNOS PDV-a: 0.00

UKUPNI IZNOS SA PDV-om: 0.00

Osnovica za PDV	Stopa PDV-a %	Iznos PDV-a
0.00	0	0.00

OPERATER:

KONTROLISAO:

RUKOVODILAC:

M.P.

ROBU PRIMIO:

Napomena: Nakon ovjerene otpremnice od strane komitenta, naknadne reklamacije se neće prihvatiti.



**DANISH EMERGENCY  
MANAGEMENT AGENCY**

Danish



**Critical Supply Agency**

**The Danish  
Ministry of Health**

## PROFORMA INVOICE

24062021-4

**This is to certify that the goods shown below are an emergency response  
and donation from the Danish Government  
to the Government of Montenegro  
*No commercial value. Value for customs purpose only.***

From / Consignor:	To / Consignee:
Danish Emergency Management Agency International Logistics Center H.P. Hansens vej 100 7400 Herning POC: B.T. Christensen, phone +45 40288589 Email: brs-ktp-mj@brs.dk  On behalf of The Danish Critical Supply Agency	Zorica Marković, MSc Head of Department for Coordination of International Assistance and Cooperation and Project Implementation Rescue and Protection Directorate Ministry of Interior of Montenegro Mobile: + 382 67 112 112 E-mail: mup.emergency.okc112@t-com.me Delivery address: Montefarm - Pharmaceutical Authority of Montenegro Ljubljanska bb - Podgorica

**Transported by:**

MAERSK, on behalf of The Danish Emergency Management Agency, The Danish Critical Supply Agency and The Danish Ministry of Health

**Shipped on lorry:**

License plate: CA 125 EH/AD 770 CA

Drivers name: Dejan Manasiev

Total volume cbm	Gross weight kgs	Description of goods	Value DKK
24,63	2479	COVID-19 AID 3.600 Surgical Gowns 76.800 FFP2 masks ~ 15 Defibrillators Lifepak 20e ~ 29 Patient Monitors Comen C90	4.867.158,00

SEE CARGO DETAILS IN LOAD MANIFEST

**Emergency aid from the Danish Government**

25/06/2021

Brian T. Christensen  
Deputy head of logistics  
Danish Emergency Management Agency



**The Danish  
Ministry of Health**

23 June 2021

*MSc Zorica Marković,  
Head of Department for Coordination of International Assistance and Cooperation and Project  
Implementation  
Ministry of Interior of Montenegro  
Rescue and Protection Directorate  
Montenegro*

**LETTER OF DONATION**

Denmark will enable a humanitarian contribution of 15 Defibrillators Lifepak 20e and 29 Patient Monitors Comen C90 from the Danish Ministry of Health on behalf of the Capital Region of Denmark to Ministry of Interior of Montenegro in support of their national COVID-19 response.



Lene Brøndum Jensen

---

Deputy Permanent Secretary  
Danish Ministry of Health

*The Danish Ministry of Health  
Holbergsgade 6  
1057 Copenhagen K  
Telephone: +45 72269000  
Mail: [sum@sum.dk](mailto:sum@sum.dk)*

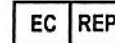




# EC Declaration Of Conformity



Physio-Control, Inc.  
11811 Willows Road NE  
Redmond, WA 98052 USA



Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

PHYSIO-CONTROL declares that the CE marked product

ITEM  
**LIFEPAK® 20e Defibrillator/Monitor**

PART NUMBER(S)  
3202487, 3202488 (New)  
U3202487, U3202488 (Remanufactured)

Conforms to European Community Council Directive 93/42/EEC (Medical Device Directive) per Annex II and is a Class IIb device in accordance with Annex IX of that Directive.

The product described above is in conformity with the requirements of the following standards:

**Safety:**

- EN 60601-1:1990 + A1 and A2  
Medical Electrical Equipment- Part 1: General Requirements for Safety
- IEC 60601-2-4:1983  
Medical Electrical Equipment – Part 2-4: Particular Requirements for the Safety of Cardiac Defibrillators
- EN 60601-2-25:1995  
Medical Electrical Equipment – Part 2-25: Particular Requirements for the Safety of Electrocardiographs

**EMC:**

- EN 60601-1-2:2001 + A1 (2004)  
Medical Electrical Equipment- Part 1-2: General Requirements for Safety- Collateral Standard: Electromagnetic compatibility- Requirements and Tests

Included are the following accessories:

**Medical**

- QUIK-COMBO® pacing/ defibrillation/ECG electrodes
- QUIK-COMBO PEDIATRIC pacing/defibrillation/ECG electrodes
- QUIK-COMBO RTS pacing/defibrillation/ECG electrodes
- QUIK-COMBO REDI-PAK™ pacing/defibrillation/ECG electrodes
- QUIK-COMBO defibrillation cable
- FAST-PATCH® PLUS defibrillation/ECG electrodes
- FAST-PATCH adapter cable
- Standard paddles with built in pediatric paddles
- External sterilizable paddles
- Internal handles with discharge controls
- Internal paddles (used with internal handles above)
- 3 wire ECG cable
- 5 wire ECG cable
- QUIK-COMBO Test Plug

**OEM Accessories - Masimo® SpO2 Monitoring**

- Patient cables: LNOP (4, 8, and 12 ft)
- Patient cables: LNCS (4, 10, and 14 ft)
- Extension cable, LNCS (4 ft)
- Reusable LNOP and LNCS sensors
- Disposable LNOP and LNCS sensors
- Disposable LNOP and LNCS sensor sample kits
- MNC-1 adapter cable (4 and 10 ft) for use with Nellcor® sensors

**OEM Accessories - Nellcor®**

- Nellcor Reusable Oximax® DS-100A Adult sensor
- Disposable Oxisensor® II sensors:
  - D-25 Adult
  - D-20 Pediatric
  - I-20 Infant
  - N-25 Neonatal/Adult
- Disposable Oximax® sensors:
  - Max-A Adult
  - Max-R Adult Nasal
  - Max-P Pediatric
  - Max-I Infant
  - Max-N Neonatal/Adult
- Non-Medical Accessories**
  - Docking Station
  - Serial cable (system connector)

Signed October 10th, 2008



Redmond, WA

This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

Paula Lank  
Vice President, Regulatory Affairs

# Shenzhen Comen Medical Instruments Co., Ltd. Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

- Electrocardiograph (Model: CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A)
    - Multi-parameter Patient Monitor for vital physiological parameters (Model: C30, C50, C70, C80, C86, C90, C500, C800, C860, NC19, NC19A, Datalys 750, Datalys 770, Datalys 780, Datalys 790, STAR8000, STAR8000A, STAR8000B, STAR8000C, STAR8000D, STAR8000E, STAR8000H, NC8, NC10, NC12, C100A, NC8A, NC10A, NC12A, C90A, C30A, C70A, STAR8000F, OPUS I8, OPUS I10, OPUS I10 Expert, OPUS I12, OPUS I12 pro, OPUS I15, K12 pro, K12A pro, K15 pro, K15A pro, K18 pro, K18A pro, K22 pro, K22A pro, K1, K1A)
  - Fetal & Maternal Monitor for vital physiological parameters (Model: STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H)
  - Specialized Fetal & Maternal Monitor for monitoring or measurement of fetal heart rate, fetal movement, uterine pressure, ECG, CO2, NIBP, SpO2, body temperature, respiration, pulse/pulse frequency (Model: C20, C26, C29, C22, C22A, C21, C21A, C10, C11)
  - Specialized Cardiovascular Monitor for processing, displaying and recording the patient's electrocardiogram and for vital physiological parameters (Model: C100, C100B)
    - Central Monitoring System Software for intensively monitoring vital physiological parameters from patient monitoring system (Model: STAR8800)
    - Vital Signs Monitor for routine check of NIBP, SpO2, Temperature and Pulse rate (Model: NC3, NC3A, NC3B, OPUS I3, NC5A)
  - Vital Signs Monitor for routine check of NIBP, SpO2, ECG, Temperature and Pulse rate (Model: NC5)
  - Specialized Neonatal Monitor for vital physiological parameters (Model: C60, C66, C68, Datalys 760)
    - Infrared Ear thermometer (Model: IRT10, IRT10A)
  - Anaesthetic Gas Scavenging System (Model: AGSS-L, AGSS-H)
    - Ceiling Pendant (Model: D5, D7, D6, D8, D9, D9A, D9B)
    - T piece Infant Resuscitation System (model: BQ70, BQ70A)
  - Anaesthesia Machine (Model: AX-400A, AX-500A, AX-700A, AX-800, AX-900, AX-900A, AX-400, AX-500, AX-600, AX-700)
    - Infant Radiant Warmer (Model: BQ80, BQ80A)
    - Catheter-positioning guiding system (Model: U8, U8A)
      - Syringe Pump (Model: M300, M500)
    - Infant Phototherapy equipment (Model: BL70, BL70A, BL70B)
  - Temperature Control System for management patient body temperature and vital physiological parameters Monitor (Model: P3, P6)
  - Sequential Compression System for prevention of deep vein thrombosis and pulmonary embolism (Model: SCD600)
    - Defibrillator Monitor (Model: S8, S6, S5, S3)
- Sterility aspect only Restricted to the Aspect of manufacture concerned with securing and maintaining sterile conditions:
- Sterile disposable laryngoscope blade (Model: CVL-2-1, CVL-3-1)
  - Sterile disposable electrode with extension wire used for Catheter-positioning guiding system (Model: 98ME01AC019)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.



EC Certificate Full Quality Assurance System: Certificate CN19/41057

The management system of

# Shenzhen Comen Medical Instruments Co., Ltd.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 22 March 2021 until 05 February 2023  
and remains valid subject to satisfactory surveillance audits.  
Issue 3. Certified since 30 April 2015.

Certification is based on reports numbered CNSZX 50010

Authorised by

Global Medical Devices Head of Notified Body

**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.