

# Certificate of Compliance



No. EC.1282.0E150114.SMA0U99

Certificate's Holder:

Shenzhen Medplus Accessory Co., Ltd.  
2nd floor, 2nd Building (Beside TianLiao Station),  
TianLiao Village, GongMing Town, Shenzhen, China

Certification Mark:



Product:

Spo2 extension cable, ECG Cable & EKG Electrode, IBP Cable, NIBP Cuff & NIBP Hose, Medical Connector & Accessory

Model(s):

MPE series, MPC series, MPK series, MPI series, MPN series, MPF series, MPJ series, MPR series, MPS-J series, MPS-L series, MPS-P series

Verification to:

Standard:  
EN ISO 14971:2012, EN 980:2008,  
EN 1041:2008, ISO 9919:2005,  
ISO 80601-2-61:2011

related to Directive(s):  
93/42/EEC (Medical Devices) and subsequent modifications and integrations  
Class I

**Remark:** The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use.

Other relevant Standards and/or Directives have to be observed in case they are applicable. Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market. The Manufacturer is responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Safety Compliance Mark. This certificate can be checked for validity at [www.entecerma.org](http://www.entecerma.org)

Date of issue 14 January 2015

Expiry date 13 January 2020

Chief Manager  
Tim Mahan



Deputy Manager  
Viola Miller



Ente Certificazione Macchine Srl

Via Ca' Belli, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY

+39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it





This is to certify that the Quality Management System of

## Shenzhen Medplus Accessory Co., Ltd.

Unified Social Credit Code : 914403003119745743

Operation Address : 2nd Floor, 1st Building, Beside Tialliao Station, Tiaoliao Community, Gongming Street, Guangming New District, Shenzhen City, Guangdong Province, China

Registered Address : 2nd Floor, 1st Building, Beside Tialliao Station, Tiaoliao Community, Gongming Street, Guangming New District, Shenzhen City, Guangdong Province, China

applicable to

Production and Sale of Spo2 sensor and ECG Cable(Only Export)

has been assessed and registered by NQA against the provisions of

### ISO 13485: 2003

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))  
SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



015

Certificate Number **42891**

Date: 30 November 2016

Valid Until: 31 March 2019

EAC Code: 19

